

No. 2022-2217

United States Court of Appeals
for the Federal Circuit

UNITED THERAPEUTICS CORPORATION,

Plaintiff-Appellee,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant-Appellant.

*Appeal from the United States District Court for the
District of Delaware, No. 20-755, Judge Richard Andrews*

**DEFENDANT-APPELLANT'S REPLY MOTION TO EXPEDITE
BRIEFING AND ORAL ARGUMENT**

SANYA SUKDUANG
JONATHAN R. DAVIES
COOLEY LLP
1299 Pennsylvania Ave NW
Washington, DC 20004
Telephone: (202) 842-7800

ERIK MILCH
COOLEY LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190
Telephone: (703) 456-8000

DEEPA KANNAPPAN
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304
Telephone: (650) 843-5000

*Counsel for Defendant-Appellant
Liquidia Technologies, Inc.*

FORM 9. Certificate of Interest

Form 9 (p. 1)
July 2020

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF INTEREST

Case Number 22-2217

Short Case Caption United Therapeutics Corporation v. Liquidia Technologies, Inc.

Filing Party/Entity Liquidia Technologies, Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box.** Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 10/06/2022

Signature: /s/ Sanya Sukduang

Name: Sanya Sukduang

FORM 9. Certificate of Interest

Form 9 (p. 2)
July 2020

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).	3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. <input checked="checked" type="checkbox"/> None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. <input type="checkbox"/> None/Not Applicable
Liquidia Technologies, Inc.		Liquidia Corporation

☐ Additional pages attached

FORM 9. Certificate of Interest

Form 9 (p. 3)
July 2020

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable

☐ Additional pages attached

Sanya Sukduang, Cooley LLP	Erik B. Milch, Cooley LLP	
Deepa Kannappan, Cooley LLP	Jonathan Davies, Cooley LLP	

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☐ None/Not Applicable

☐ Additional pages attached

United Therapeutics Corporation v. Liquidia Technologies, Inc., IPR2020-00770	United Therapeutics Corporation v. Liquidia Technologies, Inc. (Fed. Cir.) No. 22-2174	
United Therapeutics Corporation v. Liquidia Technologies, Inc., IPR2021-00406		
United Therapeutics Corporation v. Liquidia Technologies, Inc. (Fed. Cir.) No. 22-2133		

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☒ None/Not Applicable

☐ Additional pages attached

Liquidia respectfully requests the Court grant its Motion to Expedite Briefing and Oral Argument (“Mot.”) because UTC is preventing Liquidia’s YUTREPIA™ product from launching based solely on a patent—the ’793 patent—the PTAB has deemed unpatentable. The ’793 FWD differentiates this appeal from a garden-variety Hatch-Waxman case where the losing defendant seeks expedition, because the PTAB’s decision, issued *before* the district court’s decision, directly impacts and negates Liquidia’s subjective intent to induce infringement under § 271(b). The only remedy for this inequity is to expedite Liquidia’s appeal of the district court’s decision concerning the ’793 patent.¹

ARGUMENT

I. The PTAB’s ’793 FWD is Highly Relevant to This Appeal

Contrary to UTC’s assertion in its Opposition to Liquidia’s Motion (“UTC Opp.”), the PTAB’s ’793 FWD is inextricably intertwined with this appeal and its briefing schedule. UTC Opp. at 8-9. The ’793 FWD issued before the district court’s opinion on induced infringement. In light of the Supreme Court’s guidance in *Commil USA, LLC v. Cisco Systems, Inc.*, 575 U.S. 632 (2015), critical portions of which UTC overlooked in its opposition, the PTAB’s decision makes the district court’s determination that Liquidia possessed the requisite specific intent to induce

¹ Liquidia has also filed a similar motion to expedite in companion Case Nos. 2022-2133, 2022-2174.

infringement of the '793 patent legally incorrect. UTC Opp. at 9-10. *Commil* makes clear that obtaining an IPR decision as to validity, “within 12 to 18 months,” is a “proper procedure[]” to eliminate liability for induced infringement—finality upon appeal and cancellation of the patent is not needed. 575 U.S. at 644-45; *see also* 35 U.S.C. § 316(a)(11). UTC argues that infringement and invalidity are separate matters. UTC Opp. at 10. In fact, this difference is the reason why the district court’s requirement that collateral estoppel apply before the PTAB’s decision can impact Liquidia’s subjective intent is incorrect. Mot. Ex. 3 at 36-37. As will be demonstrated on appeal, whether a PTAB’s FWD has collateral estoppel effect for validity has no bearing on its impact upon the *subjective intent of an accused infringer* to induce infringement.

Further, because UTC filed a rehearing request, which will delay UTC’s appeal of the PTAB’s ’793 FWD for an indeterminate period of time, expediting this appeal is warranted.² Indeed, UTC’s opposition treats the ’793 FWD rendering all claims unpatentable as if it never happened because those claims have not yet been “cancelled.” UTC Opp. at 8-9. But the PTAB did render unpatentable the ’793

² The Court has expressed significant frustration over the PTAB’s delay in deciding rehearing requests, noting during oral argument in *BTG International Ltd. v. Amneal Pharmaceuticals LLC*, No. 2019-1147 (Fed. Cir. Mar. 14, 2019) that PTAB delays significantly undermine Congressional intent for IPRs to be expeditious proceedings. Ex. 8 at 32:23-33:8, 34:22-35:1.

patent, and that decision is important to the parties' legal proceedings and the PAH population at large³.

Finally, that the PTAB found each claim of the '793 patent unpatentable, but the district court found the asserted claim valid, albeit under different invalidity challenges, does not minimizing the conflict on validity—a conflict that can be resolved by expediting this appeal. UTC Opp. at 11.⁴

II. UTC's Litigation Decisions Led Directly to the PTAB's '793 FWD

UTC asserts that because of "Liquidia's own conduct" in filing an IPR, expediting this appeal is not warranted. UTC Opp. at 12-13. UTC's opposition omits critical facts. Liquidia's '793 IPR was necessitated by UTC's decision to argue, up to the eve of trial, that Liquidia cannot challenge the validity of the '793 patent in district court due to assignor estoppel. Specifically, UTC moved to dismiss Liquidia's invalidity defenses with respect to the '793 patent based on assignor estoppel (Ex. 13), which the Court denied (Ex. 14). UTC, however, pursued its

³ UTC contends the needs of the PAH population are met by UTC's treprostinil product portfolio, including its own dry powder formulation of treprostinil. UTC Opp. at 7 n.1. To the contrary, PAH patients and healthcare providers are still demanding YUTREPIA™, despite UTC's current offerings. *See* Exs. 9-12.

⁴ UTC notes that Liquidia did not address the district court's findings concerning § 112 in its motion to stay judgment. UTC Opp. at 11 n.2. That Liquidia choose to raise other reasons why it is likely to succeed on appeal, including non-infringement, does not concede the district court's §112 conclusions were legally or factually correct.

assignor estoppel defense, including it in its pre-trial submissions.⁵ Ex. 15, ¶¶ 136-140. Because assignor estoppel does not apply to IPR proceedings, Liquidia filed the '793 patent IPR to ensure at least some of its invalidity arguments were preserved. *Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 804 (Fed. Cir. 2018).

While UTC alleges that Liquidia “abandon[ed]” its '793 patent obviousness arguments at trial (UTC Opp. at 12), UTC advocated in its *pre-trial submissions*, before the '793 FWD issued, that Liquidia should be prevented from raising obviousness due to IPR estoppel. Ex. 15, ¶ 146. Although denying UTC’s motion, the district court indicated that it would apply IPR estoppel even if Liquidia raised obviousness of the '793 patent at trial. Ex. 16 at 10-11. Thus, rather than waste trial time on an issue the district court would not decide—and UTC advocated removing from trial—Liquidia pursued only § 112 invalidity theories with respect to the '793 patent. As such, UTC has no legitimate basis to oppose expediting this appeal based on Liquidia’s successful IPR when its own assignor estoppel and IPR estoppel arguments forced this course of action.

⁵ UTC did not ultimately try the issue of assignor estoppel.

III. UTC Will Not be Prejudiced

UTC asserts an expedited schedule will be prejudicial because the schedule is faster than what is normally permitted under the rules. UTC Opp. at 13. But that is the very nature of an expedited schedule. If a faster schedule, alone, was sufficient to establish prejudice, then no expedited schedule could ever be granted. Moreover, during the parties' conference to discuss expediting this appeal, Liquidia offered to consider modifications to its proposed schedule. UTC was unwilling to offer an alternative expedited schedule and instead simply indicated its opposition. Even in its opposition brief, UTC did not provide alternative dates. Failing to articulate a real prejudice, or offer a compromised schedule, the Court should adopt Liquidia's proposed briefing schedule.

IV. Expediting Both This Appeal and UTC's Appeal of the '901 IPR Is Warranted

UTC asserts that Liquidia can expedite its own briefing, resolving this issue for this appeal. UTC Opp. at 12-13. However, because UTC has appealed the PTAB's FWD of the '901 patent (Case Nos. 2022-2133, 2022-2174), the respective appeals have been designated companion cases and will be heard on the same day by the same panel. As such, unilateral expedition of briefing in this appeal will not result in earlier resolution of the district court's decision on the '793 patent because oral argument on this appeal will be delayed due to the '901 FWD appeal briefing schedule. As a result, and contrary to UTC's position, resolution of the '901 FWD

appeal does impact Liquidia's ability to launch YUTREPIA™. UTC Opp. at 13. Expediting this appeal as well as the '901 FWD appeal is needed.⁶

UTC also complains that it should not be forced to file its '901 FWD appeal on an expedited basis. UTC Opp. at 13-14. But appeal of the '901 IPR has already been delayed for a year. The PTAB issued its '901 IPR FWD on October 8, 2021. Ex. 17. UTC filed a request for rehearing on November 8, 2021, and the Board denied UTC's request for rehearing June 14, 2022—i.e., over 7 months after the FWD issued. Ex. 18. It was not until August 15, 2022, that UTC filed its notice of appeal, giving UTC a year to prepare its appeal strategy and briefing. Given the totality of the circumstances, granting Liquidia's proposed expedited schedule for both appeals is not burdensome to UTC.

CONCLUSION

For the foregoing reasons, Defendant-Appellant Liquidia, respectfully requests that the Court expedite briefing and oral argument in Case No. 2022-2217, in accordance with the following schedule, which has been updated to account for UTC's cross-appeal:

⁶ UTC alternatively suggests the Court “decouple” the district court and '901 IPR appeals such that they proceed on independent tracks. UTC Opp. at 14. Liquidia would be amenable to this proposal assuming oral argument from the district court appeal is not delayed to coincide with oral argument associated with the '901 IPR appeal.

Filing	Expedited Due Date
Defendant-Appellant's Opening Briefs	10/14/2022
Plaintiff-Appellee's Responsive Briefs Plaintiff-Appellant's Opening Brief	11/03/2022
Defendant-Appellant's Reply Brief Defendant-Appellant's Response Brief	11/23/2022
Plaintiff-Appellee's Reply Brief	12/5/2022
Oral Argument	Next available date after briefing is complete

Dated: October 6, 2022

Respectfully submitted,

/s/ Sanya Sukduang
Sanya Sukduang
Jonathan R. Davies
Cooley LLP
1299 Pennsylvania Ave., NW
Suite 700
Washington, DC 20004
Telephone: (202) 842-7800
Facsimile: (202) 842-7899

Deepa Kannappan
Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
Telephone: (650) 843-5000
Facsimile: (650) 849-7400

*Counsel for Defendant-Appellant Liquidia
Technologies, Inc.*

CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d) and 32(a) and has been prepared using a proportionally-spaced typeface and includes 1,449 words.

Dated: October 6, 2022

/s/ Sanya Sukduang

Sanya Sukduang
Cooley LLP

*Counsel for Defendant-Appellant
Liquidia Technologies, Inc.*

LIST OF EXHIBITS

Ex. 8	<i>BTG Int'l Ltd. v. Amneal Pharms. LLC</i> , No. 2019-1147, Oral Argument Hearing Transcript (Fed. Cir. Mar. 14, 2019)
Ex. 9	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 439-17, Exhibit Q, Email from Melly Meadows McCutcheon (D. Del. Sept. 9, 2022)
Ex. 10	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 439-25, Exhibit Y, Email from Shirley J. Craig (D. Del. Sept. 9, 2022)
Ex. 11	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 439-26, Exhibit Z, Email from Tracey Considine (D. Del. Sept. 9, 2022)
Ex. 12	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 444-4, Exhibit DD, Letter from PAH Physicians (D. Del. Sept. 28, 2022)
Ex. 13	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 28, UTC's Motion to Dismiss Liquidia's Invalidity Counterclaims and Defenses (D. Del. Aug. 26, 2020)
Ex. 14	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 45, Order Denying UTC's Motion to Dismiss Liquidia's Counterclaims (D. Del. Nov. 3, 2020)
Ex. 15	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 365, Ex. 4, UTC's Statement of Contested Issues of Law (D. Del. Feb. 28, 2022)
Ex. 16	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 367, Pretrial Conference Transcript (D. Del. Mar. 4, 2022)
Ex. 17	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 20-755, ECF No. 205, Notice of Subsequent Authority (D. Del. Oct. 12, 2021)

Ex. 18	<i>Liquidia Technologies, Inc. v. United Therapeutics Corp.</i> , IPR2020-00770, Paper 49, Denying UTC's Request for Rehearing of Final Written Decision (P.T.A.B. June 14, 2022)
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EXHIBIT 8



Deposition of:
Transcription 03/14/2019

October 26, 2021

In the Matter of:
**BTG International Limited Vs. Amneal
Pharmaceuticals LLC**

Veritext Legal Solutions
800-734-5292 | calendar-dmv@veritext.com |

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BTG INTERNATIONAL LIMITED,)
JANSSEN BIOTECH, INC.,)
JANSSEN ONCOLOGY, INC.,)
JANSSEN RESEARCH &)
DEVELOPMENT, LLC,)
Plaintiffs-Appellants,)
v.)
AMNEAL PHARMACEUTICALS LLC,) March 14, 2019
AMNEAL PHARMACEUTICALS OF)
NEW YORK, LLC, DR. REDDY'S)
LABORATORIES, INC., DR.)
REDDY'S LABORATORIES, LTD.,)
WOCKHARDT BIO AG, WOCKHARDT)
USA LLC, WOCKHARDT LTD.,)
MYLAN PHARMACEUTICALS INC.,)
MYLAN INC., WEST-WARD)
PHARMACEUTICALS CORP., NKA)
HIKMA PHARMACEUTICALS USA)
INC., HIKMA PHARMACEUTICALS)
LLC, TEVA PHARMACEUTICALS)
USA, INC,)
Defendants-Appellees,)
PAR PHARMACEUTICAL, INC., PAR)
PHARMACEUTICAL COMPANIES,)
INC., RISING PHARMACEUTICALS,)
INC.,)
Defendants.)

NO. 2019-1147

ON APPEAL FROM THE ORDER OF THE
UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW JERSEY

CASE NOS.: 2:15-cv-05909-KM-JBC; 2:17-cv-06435-KM-JBC

1 BTG INTERNATIONAL LIMITED,)
JANSSEN BIOTECH, INC.,)
2 JANSSEN ONCOLOGY, INC., AND)
JANSSEN RESEARCH &)
3 DEVELOPMENT, LLC,)

4 Plaintiffs-Appellants,)

5 v.)

6 AMERIGEN PHARMACEUTICALS,)
INC., AMERIGEN)
7 PHARMACEUTICALS LIMITED,)

8 Defendants-Appellees.)

NO. 2019-1148

9
10 ON APPEAL FROM THE ORDER OF THE
UNITED STATES DISTRICT COURT FOR THE
11 DISTRICT OF NEW JERSEY
CASE NO. 2:16-CV-02449-KM-JBC

12 JANSSEN ONCOLOGY, INC.,)

13 Appellant,)

14 v.)

15 AMERIGEN PHARMACEUTICALS)
16 LIMITED, ARGENTUM)
PHARMACEUTICALS LLC,)

17 Appellees.)

18 NO. 2019-1323

19
20 ON APPEAL FROM THE ORDER OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT TRIAL AND APPEAL BOARD
21 NOS. IPR2016-00286 AND IPR2016-01317
22
23
24
25

1 JANSSEN ONCOLOGY, INC.,)
2 Appellant,)
3 v.)
4 MYLAN PHARMACEUTICALS INC.,)
5 AMNEAL PHARMACEUTICALS LLC,)
6 AMNEAL PHARMACEUTICALS OF)
7 NEW YORK, LLC, DR. REDDY'S)
8 LABORATORIES, INC., DR.)
9 REDDY'S LABORATORIES, LTD.,)
10 TEVA PHARMACEUTICALS USA,)
11 INC., WEST-WARD)
12 PHARMACEUTICAL CORPORATION,)
13 HIKMA PHARMACEUTICALS LLC,)
14 Appellees.)

NO. 2019-1324

12 ON APPEAL FROM THE ORDER OF THE
13 UNITED STATES PATENT AND TRADEMARK OFFICE
14 PATENT TRIAL AND APPEAL BOARD
15 NOS. IPR2016-01332 AND IPR2017-00853
16 JANSSEN ONCOLOGY, INC.,)
17 Appellant,)
18 v.)
19 WOCKHARDT BIO AG,)
20 Appellee.)

NO. 2019-1325

19 ON APPEAL FROM THE ORDER OF THE
20 UNITED STATES PATENT AND TRADEMARK OFFICE
21 PATENT TRIAL AND APPEAL BOARD
22 NO. IPR2016-01582
23
24
25

BEFORE APPELLATE PANEL:

HON. KIMBERLY A. MOORE, Circuit Judge

HON. EVAN J. WALLACH, Circuit Judge

HON. RAYMOND T. CHEN, Circuit Judge

APPEARANCES

(see next page)

Veritext National Court Reporting Company

1801 Market Street

Suite 1800

Philadelphia PA 19103

(888) 777-6690

1 APPEARANCES:

2 For the Plaintiffs-Appellants Janssen Biotech, Inc.,
3 Janssen Oncology, Inc., Janssen Research &
4 Development, LLC:

5 CONSTANTINE L. TRELA, JR., ESQ.
(Argued)

6 STEVEN J. HOROWITZ, ESQ.

7 DAVID T. PRITIKIN, ESQ.

8 THOMAS D. REIN, ESQ.

9 SIDLEY AUSTIN LLP

10 One South Dearborn

11 Chicago, IL 60603

12 ALYSSA B. HJEMDAHL-MONSEN, ESQ.

13 SIDLEY AUSTIN LLP

14 787 Seventh Avenue

15 New York, NY 10019

16 RYAN C. MORRIS, ESQ.

17 CARTER G. PHILLIPS, ESQ.

18 PAUL J. ZEGGER, ESQ.

19 SIDLEY AUSTIN LLP

20 1501 K Street, N.W.

21 Washington, D.C. 20005

22 For the Plaintiff-Appellant BTG International Ltd.:

23 ANTHONY C. TRIDICO, ESQ.

24 JENNIFER HOWE ROSCETTI, ESQ.

25 FINNEGAN, HENDERSON, FARABOW,

GARRETT & DUNNER, LLP

901 New York Avenue, NW

Washington, DC 20001

1 For the Defendants-Appellees Mylan Inc., Mylan
2 Pharmaceuticals Inc.:

3 NATHAN K. KELLEY, ESQ. (Argued)
4 BRANDON M. WHITE, ESQ.
5 SHANNON M. BLOODWORTH, ESQ.
6 PERKINS COIE, LLP
7 700 Thirteenth Street, NW
8 Washington, DC 20005
9 DAN L. BAGATELL, ESQ.
10 PERKINS COIE LLP
11 3 Weatherby Road
12 Hanover, NH 03755

13 DAVID LEE ANSTAETT, ESQ.
14 ANDREW DUFRESNE, ESQ.
15 PERKINS COIE LLP
16 33 East Main Street
17 Suite 201
18 Madison, WI 53703

19 For the Defendants-Appellees Amneal Pharmaceuticals
20 LLC, Amneal Pharmaceuticals of New York, LLC, Dr.
21 Reddy's Laboratories, Inc., Dr. Reddy's Laboratories,
22 Ltd., West-Ward Pharmaceuticals Corp. n/k/a Hikma
23 Pharmaceuticals LLC, Teva Pharmaceuticals USA, Inc.:

24 CHARLES B. KLEIN, ESQ.
25 JOVIAL WONG, ESQ.
ANDREW C. NICHOLS, ESQ.
WINSTON & STRAWN LLP
1700 K Street NW
Washington, DC 20006

For the Defendants-Appellees Wockhardt Bio AG,
Wockhardt USA LLC, Wockhardt Ltd.:

DENNIES VARUGHESE, ESQ.
STERNE KESSLER GOLDSTEIN & FOX, PLLC
1100 New York Avenue, NW
Washington, DC 20005

1 For the Defendants-Appellees Amerigen Pharmaceuticals,
2 Inc., Amerigen Pharmaceuticals Limited:

3 WILLIAM D. HARE, ESQ.
4 CHRISTOPHER CASIERI, ESQ.
5 MCNEELY, HARE & WAR, LLP
6 5335 Wisconsin Avenue, NW
7 Suite 440
8 Washington, DC 20015

9 For the Appellee Argentum Pharmaceuticals LLC:

10 TERESA STANEK REA, ESQ.
11 Crowell & Moring, LLP
12 1001 Pennsylvania Avenue, NW
13 11th Floor
14 Washington, DC 20004

15 For the Amicus Curiae Andrei Iancu:

16 THOMAS W. KRAUSE, ESQ. (Argued)
17 Office of the Solicitor
18 United States Patent and
19 Trademark Office
20 600 Dulany Street
21 Alexandria, VA 22314

22 FRANCES LYNCH, ESQ.
23 JOSEPH MATAL, ESQ.
24 ROBERT J. MCMANUS, ESQ.
25 FARHEENA Y. RASHEED, ESQ.
MARK R. FREEMAN, ESQ.
SCOTT R. MCINTOSH, ESQ.
JENNIFER UTRECHT, ESQ.
Civil Division
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

1 For the Amicus Curiae Association for Accessible
2 Medicines:

3 WILLIAM M. JAY, ESQ.

4 GOODWIN PROCTER LLP

5 1900 N Street NW

6 Washington, DC 20036

7 JOSHUA J. BONE, ESQ.

8 JEFFREY FRANCER, ESQ.

9 GOODWIN PROCTER LLP

10 100 Northern Avenue

11 Boston, MA 02210

1 P R O C E E D I N G S

2 HON. MOORE: Our only case on the
3 docket this morning is 2019-1147, BTG International
4 Limited v. Amneal Pharmaceuticals. Mr. Trela, please
5 proceed.

6 MR. TRELA: Thank you, Your Honor. May
7 it please the Court.

8 The treatment method claimed in the 438
9 patent revolutionized the treatment of advanced
10 prostate cancer.

11 HON. WALLACH: Mr. Trela, you're not
12 going to like my first question but you'll answer it
13 for me.

14 This appeal consolidates the PTAB in
15 the district court (indiscernible). If we affirmed
16 the PTAB's claim construction, that renders the rest
17 of the appeal moot, right?

18 MR. TRELA: No. I don't think it does,
19 Your Honor, for a couple of reasons. The first is, as
20 we suggested in our reply brief when the appellees
21 raised the mootness question, Janssen may have a cause
22 of action for the -- basically, the period of
23 statutory exclusivity that it lost prematurely if
24 we're right about what 315(e)(2) means. That hasn't
25 been explored. We would submit that that should be

1 explored on remand.

2 Beyond that, though, it would certainly
3 not -- I think if you put that aside, if you affirm
4 the PTAB, I think you could avoid -- you could choose
5 to avoid the 315(e)(2) issue but you wouldn't be
6 required to. I think you would have the power to
7 decide it. It's not moot in any sort of a
8 jurisdiction.

9 HON. MOORE: Why the heck would we want
10 to decide that question if it's not necessary to the
11 resolution of the case. It is a large issue of
12 statutory interpretation. Why would -- I mean, it
13 seems like doctrines, like, say, constitutional
14 avoidance ring in my ears when I think about something
15 like this and think if there is a very narrow way to
16 decide this case, why should we decide it -- go the
17 extra step unnecessarily unrequired and decide a
18 really bigger important issue?

19 MR. TRELA: Well, it is precisely
20 because it is a big important issue, Your Honor, that
21 I think you should decide it. This Court, as do other
22 appellate courts -- it's not at all unusual for the
23 Court to say, well, we -- although we technically
24 don't have to reach this issue having decided this
25 other issue, this is an issue on which lower courts

1 and litigants need guidance. It -- and that is
2 particularly true --

3 HON. MOORE: But why? How many -- I
4 have never seen a case other than this one which has
5 raised this issue or in which it has been a problem.
6 So do you have any evidence to suggest to me that this
7 is a pervasive issue that is arising in a number of
8 cases? I didn't see it in your briefing.

9 MR. TRELA: Well, we did point out in
10 our briefs that another district court and an ITC ALJ
11 have read the statute our way. That is, that --

12 HON. MOORE: Well, that would suggest
13 that it's really not an issue because that would
14 suggest that there's one aberrational court that may
15 have read it incorrectly in your view but that
16 incorrect decision is entirely mooted by the PTO
17 action. So why should I reach out and decide that
18 issue when all of the other courts to have addressed
19 have actually agreed with you?

20 MR. TRELA: Well, clearly, all the
21 other courts haven't because the district court here
22 didn't.

23 HON. MOORE: All the other courts.

24 MR. TRELA: All -- I misunderstood.
25 And also, I think that you have an amicus -- actually,

1 you have amici on both sides of the issue I think
2 pointing out that there is a legitimate dispute here
3 about -- we have the amici -- amicus who filed on
4 behalf of the appellees basically saying that this is
5 going to bring the Hatch-Waxman Act to its knees if
6 you don't clarify exactly what this statute means. On
7 the other hand, we have the PTO basically saying you
8 should apply this as we do saying you should apply the
9 statute as written. So there is a -- as Your Honor
10 said, it's an important issue squarely presented here.
11 It's not moot as the -- you know, the Supreme Court
12 decisions like *Already v. Nike* and *Cardinal Chemical*
13 make clear --

14 HON. MOORE: But I guess, I still am
15 not seeing the evidence. I hear your rhetoric. But
16 I'm not seeing the evidence that this is an important
17 issue beyond the facts that it's just an interesting
18 question of statutory interpretation. And what I mean
19 by important is the impact this issue is having on
20 existing litigation. I don't personally see evidence
21 that there are lots of courts struggling with it or
22 making the wrong decision or there's one court that
23 potentially made the wrong decision in your view and
24 that entire decision would be mooted. We could even
25 vacate it by virtue of its being mooted in this case.

1 So I am not sure that anything you've
2 said to me justifies the need to add clarity to the
3 law and that there are really a lot of people impacted
4 by this.

5 MR. TRELA: Well, Your Honor, I can't
6 point you to dozens of cases coming out the other way.
7 What I can tell you is obviously one court did in this
8 case. Also, if you look at -- and it was not in the
9 briefs before this Court although it is in the
10 district court briefing. There are, I think it's fair
11 to say, dozens of district court opinions where the
12 isn't squarely presented because you didn't have the
13 precise lineup of the parties that we have here. But
14 the courts describe the statute in ways that really
15 cut both ways. Some describe it in terms that it's an
16 estoppel that applied broadly. Others --

17 HON. MOORE: But in none of those cases
18 is the issue present. So why in the world would this
19 panel not wait till a case where it actually matters
20 to decide it.

21 MR. TRELA: Well, you -- as I said, you
22 could avoid the question. The problem, I think, is if
23 you wait in the meantime, the uncertainty persists and
24 you have district courts in cases where there's an IPR
25 proceeding either going on or where a final written

1 decision has issued not knowing what is the proper way
2 to handle infringement allegations. And so you have,
3 basically, the danger of multiple litigation of the
4 invalidity issues when that's exactly what, under our
5 view, Congress meant to prevent in 315(e)(2).

6 HON. CHEN: When the patent board
7 issued three different IPR decisions in January of
8 2018 finding all of the claims of this patent
9 unpatentable, why didn't the district court just stop
10 any further work on the district court action? Why
11 didn't the district court just stay the state of the
12 district court action right then and there?

13 MR. TRELA: Well, we filed a motion in
14 the district court saying you shouldn't consider
15 invalidity anymore because of 315(e)(2) and the
16 issuance of the final written decisions. There were
17 still the infringement issue --

18 HON. CHEN: Right. But my -- and my
19 larger point is why keep going with any aspect of the
20 district court litigation given that there were now
21 three different decisions finding three different
22 rationales for finding all of the claims unpatentable.
23 What was -- why keep going? Why go ahead and have a
24 full trial?

25 MR. TRELA: Well, certainly, obviously

1 as I said, we didn't think invalidity should be tried
2 at that point. I don't think anybody asked the Court
3 to suspend proceedings on the infringement part of the
4 case pending -- I assume what Your Honor's point is
5 waiting till this -- the appeals from the final
6 written decisions ran their course and then just enter
7 judgment one way or the other.

8 HON. MOORE: No. We're just wondering
9 why you didn't move for a stay in the district court
10 of all of this.

11 MR. TRELA: Well --

12 HON. MOORE: That seems like the most
13 logical way to have proceeded.

14 MR. TRELA: Well, it's --

15 HON. MOORE: Especially given what you
16 say is necessary to avoid which is duplicative
17 litigation between the PTO and the district court.

18 MR. TRELA: Well, and had invalidity
19 been the only issue, it would have been a different
20 situation. But we still had to prove infringement.
21 And obviously, we are -- our intention, as I'm
22 standing here today proves, was to challenge the PTO
23 determinations -- the PTAB determinations on
24 invalidity. And had if we succeed on that and
25 infringement hadn't been tried, then you'd go back for

1 a trial. And meanwhile, the 30 months --

2 HON. MOORE: But you could have
3 obviated -- you could have obviated all of the parade
4 of horrors you're suggesting to me could possibly
5 exist by simply moving to stay the district court.

6 MR. TRELA: Well --

7 HON. MOORE: And that -- so you want us
8 to go out of our way to decide an issue of statutory
9 interpretation which no other Court but this one has,
10 in your view, decided wrongly and all the other Courts
11 are deciding it correctly. You nonetheless want this
12 Court to tackle it, challenge it, go through it and
13 adjudicate it and resolve it even though it's
14 unnecessary in this case and you're saying because it
15 could cause duplicative litigation and problems in the
16 future. But I think that we've just shown multiple
17 ways in which that could be avoided by the parties.
18 And so I'm not certain that you have, by any means,
19 justified why this Court should reach out to decide an
20 issue that's unnecessary in a case.

21 MR. TRELA: Well, Your Honor, the
22 duplicative litigation part of it was considering
23 invalidity. The infringement part was not
24 duplicative. The only place that could be heard was
25 in the district court. Now certainly, if the Court

1 had stayed the case, and obviously --

2 HON. MOORE: Yes. But your client
3 shouldn't want to be paying for lawyer services to
4 resolve an infringement of a patent for which multiple
5 IPRs have been granted across all of the claims. Why
6 in the world would your -- why is it in your client's
7 best interest to proceed even with the infringement
8 portion given that the PTO could well invalidate --
9 granted that they accepted the IPR on multiple IPRs --
10 challenging all of the claims that the chances are at
11 the end of the day they're going to invalidate it?
12 Why would anybody but the lawyers for your client make
13 out by your client not staying this case?

14 MR. TRELA: Well, Your Honor, I can
15 assure you that the lawyers didn't drive any
16 decisions. It was clearly the client's decision --

17 HON. MOORE: Well, clients are not
18 always (indiscernible).

19 MR. TRELA: Well, my clients are but
20 that's a separate topic.

21 Your Honor, the --

22 HON. MOORE: It's your job to reign
23 them in.

24 MR. TRELA: Well, as anybody who's been
25 in private practice knows that it's --

1 HON. WALLACH: Let me take you
2 somewhere else for a moment, if I may, Mr. Trela.

3 Is claim one of (indiscernible) patent
4 representative?

5 MR. TRELA: I believe it is, Your
6 Honor, yes.

7 HON. WALLACH: Okay. You cite in a
8 section titled "Definitions of Patent" explains
9 your -- you're at 30 of your (indiscernible):

10 "As used herein, and unless otherwise
11 defined, the terms 'treat', 'treating' and 'treatment'
12 include the eradication, removal, modification,
13 management or control of a tumor or primary, regional,
14 or metastatic cancer cells or tissue".

15 MR. TRELA: Yes.

16 HON. WALLACH: Okay? Can't
17 "management" reasonably be interpreted as keeping the
18 patient in shape to continue treatment?

19 MR. TRELA: I don't think so, Your
20 Honor.

21 HON. WALLACH: Why?

22 MR. TRELA: Well, because it says -- it
23 doesn't say management -- obviously, it doesn't say
24 management of the patient. It also doesn't say
25 management of the cancer. It says management of the

1 tumor, the cancer cells and the tissues. And I think
2 that makes --

3 HON. WALLACH: If you're doing a broad
4 interpretation of what reasonably can be interpreted
5 of "management", why doesn't that include keeping the
6 person in a condition such that you can do those other
7 things to the tumor?

8 MR. TRELA: Well --

9 HON. WALLACH: Which, of course, brings
10 in everything else.

11 MR. TRELA: Exactly. For several
12 reasons, Your Honor. One is, as I said, I think the
13 focus on tissue tumors, cells, I think, argues against
14 that. It may not preclude it but I think it argues
15 against it.

16 The other point is that the entire
17 patent -- there's not any mention at all of side
18 effects, of pain, of palliation, anything like that.
19 It's also focused strictly on treating the cancer.
20 The definition of therapeutically effective amount
21 when the patent talks about how much of each of the
22 different agents should be administered. It's an
23 amount effective to treat the cancer. So I think in
24 the context of this patent, even the controlled or
25 management language there, I think is focused on

1 treatment of the cancer itself meaning the cells,
2 tissue, tumors.

3 HON. CHEN: The specification defines
4 the second agent can be combined with the CYP
5 inhibitor as being either an anti-cancer agent or a
6 steroid.

7 MR. TRELA: Correct.

8 HON. CHEN: So that suggests that
9 steroid is not necessarily the same thing as an anti-
10 cancer agent.

11 MR. TRELA: Well, I think -- I have a
12 couple of responses. One is, the amount of the
13 steroid that is to be given is an amount that is
14 effective to treat the cancer. So even if --

15 HON. WALLACH: But that can include
16 management.

17 MR. TRELA: Well, that circles back --
18 it obviously circles back to what "treating" means.
19 But I think Judge Chen's question may be a little bit
20 broader than that.

21 HON. WALLACH: It's an "or" question,
22 yeah.

23 MR. TRELA: Right. Right. The -- and
24 it says "amount effective to treat the cancer". So
25 it's foc -- even though steroids -- obviously,

1 steroids can have all sorts of other effects. None of
2 them are mentioned here. And what it's talking about
3 is the use of the steroid to treat the cancer.
4 Putting to one side what "treat" means in this
5 context.

6 HON. CHEN: So you want me to read
7 "anti-cancer effects" or "anti-cancer agent or
8 steroid" as being translated to anti-cancer agent or
9 another kind of anti-cancer agent called a steroid.

10 MR. TRELA: Well, I think in the con --
11 particularly in the context here where we're talking
12 about prednisone -- and prednisone is included as an
13 anti-cancer agent. It -- because it's an anti --
14 anti-cancer agents include antibiotics. Antibiotics
15 are defined to include prednisone. So I think in the
16 context of this specification and these claims, in
17 fact, it does mean anti-cancer agent, a CYP17
18 inhibitor plus another anti-cancer agent, in this case
19 prednisone. And I think --

20 HON. CHEN: Well, then why did the
21 specification say "anti-cancer agent or steroids"?
22 That's what I don't understand from --

23 HON. WALLACH: And could it reasonably
24 be read that way?

25 MR. TRELA: Well, I don't -- I think

1 the explanation for why the specification is as it is,
2 is -- the specification is quite a bit broader than
3 the claims. The specification, as Your Honor noted,
4 talks about steroids. It talks about --

5 HON. CHEN: I don't know. The claim is
6 pretty broad.

7 MR. TRELA: Well, the -- well --

8 HON. CHEN: It says treat cancer using
9 element 1, element 2 --

10 MR. TRELA: Right.

11 HON. CHEN: -- (indiscernible), period.

12 MR. TRELA: Well, except that it's
13 saying exactly what element 1 and element 2 are
14 whereas the specification, obviously, is talking about
15 all sorts of different agents some of which may have
16 anti-cancer effects alone, some of which may only have
17 them, as prednisone does, when used in combination.

18 HON. MOORE: Well, time out. I'm not
19 sure that I understand that to be the record in this
20 case. And the one thing that was bothering me is that
21 your briefing fails to entirely address the Wockhardt
22 IPR and the separate finding which I'll say scan pages
23 349 to 351 of the brief of the appendix wherein the
24 PTO makes an express finding that Sartor establishes
25 that Prednisone alone was being used effectively in

1 some kinds of patients to treat prostate cancer. Even
2 under your construction of the claim, that is an
3 independent fact finding in that IPR which invalidates
4 all the claims. And I can't see that you addressed it
5 --

6 MR. TRELA: Well --

7 HON. MOORE: -- anywhere in your
8 briefing.

9 MR. TRELA: Well, I think we did, Your
10 Honor. And we did it in a couple of ways. First of
11 all --

12 HON. MOORE: Where? Why don't you tell
13 me where in your briefing you addressed that separate
14 fact finding that is an independent basis for
15 affirming the entire PTO decision even under your
16 claim construction?

17 If you want to do it on rebuttal, you
18 can.

19 MR. TRELA: Well, I -- yeah. Let me --

20 HON. MOORE: Do you want to do that?

21 MR. TRELA: -- do that.

22 HON. MOORE: I'm going to restore
23 rebuttal time.

24 MR. TRELA: Okay.

25 HON. MOORE: It's a complicated case.

1 MR. TRELA: It is. But I'll find you
2 the exact pages and I'll give you that on rebuttal.
3 But if I can take a minute now, I think I can address
4 what I believe we said in the brief which is a couple
5 of things. One is, nobody -- the Board didn't suggest
6 and appellees don't suggest that the Board applied
7 that -- let's call it the alternate claim construction
8 wanted to address objective indicia and it clearly did
9 not focus solely on abiraterone alone as the anti-
10 cancer element of the invention. There's no
11 suggestion anywhere in this discussion of objective
12 indicia that it was applying -- let's call it the
13 Wockhardt or the alternate claim construction.

14 The other thing is, that even as to the
15 -- what the Board said about Sartor and supposed anti-
16 cancer effects of prednisone -- and there are problems
17 with that but I won't go into those right now. The
18 Board never found that there was a reasonable
19 expectation of success improving -- in providing a
20 cancer treatment in which prednisone, in the
21 combination, has an anti-cancer effect. And, in fact,
22 it could not have made that finding because --

23 HON. MOORE: Can you explain to me how
24 the claim construction affected the Board's -- or
25 infected in your view, the Board's analysis of the

1 objective consideration? There was some commercial
2 success evidence. There was this unexpected or
3 long-felt need. Tell me how -- show me in the Board
4 opinion how you believe that their wrongheaded claim
5 construction led them to the wrong conclusion about
6 this objective indicia.

7 MR. TRELA: Sure. Let me take -- just
8 as an example, the Board's discussion of unmet need,
9 long felt --

10 HON. MOORE: Show me what page in the
11 Board's opinion, please.

12 MR. TRELA: Well, let's look at -- and
13 I think they're all the same on this -- Appendix 366.
14 That's in Wockhardt.

15 HON. MOORE: Okay.

16 MR. TRELA: And so what the Board says
17 is -- and it's -- here again, it's focusing solely on
18 abiraterone saying abir -- there was no unmet need
19 because abiraterone had been available and
20 underutilized for a decade. And so that showed that
21 there was no unmet need for an abiraterone-based
22 therapy. But the problem is the therapy is not --
23 it's not limited to abiraterone. It's abiraterone
24 plus prednisone --

25 HON. MOORE: But you can say that but

1 that's -- you directed me to page 366. And I'm
2 looking at the section on long-felt need. And in
3 every single sentence, the Board says "administering
4 abiraterone acetate and prednisone". So I don't
5 understand how their analysis could be read the way
6 you just articulated it in court when they are careful
7 to link the two together in their discussion.

8 MR. TRELA: Well, because I think if
9 you look at the analysis, what they're saying is
10 abiraterone was underutilized and that shows that
11 there was no unmet need. But that's not the relevant
12 inquiry because the rel -- the long-felt need was not
13 for a treatment based on abiraterone. It was for a
14 treatment that was effective. And it was only because
15 of the combination and the anti-cancer effect of
16 prednisone that that need was met by this claimed
17 invention.

18 Another example, Your Honor, is
19 commercial success. There, the Board completely
20 discounted any anti-cancer effect of prednisone and
21 essentially said commercial success was driven by
22 abiraterone. Abiraterone was in the prior art;
23 therefore, there was -- the commercial success was
24 not --

25 HON. MOORE: No. No --

1 MR. TRELA: -- attributable --

2 HON. MOORE: -- no. You're saying
3 these things out loud in court but I'm looking on page
4 367. "[B]oth abiraterone and prednisone were well
5 known in the prior art, as was administering
6 prednisone with other anticancer agents,
7 including...inhibitors" and other things. It seems to
8 me -- and then it talks about Zytiga sales -- I mean,
9 I don't know. I -- "are driven by the benefits of
10 adding prednisone to the treatment". Is that -- I
11 mean, is that the sentence that you think supports the
12 (indiscernible) raising -- what are the -- I am just
13 struggling to see how your vision of the claim
14 construction rendered the fact findings on objective
15 consideration infected and wrong. I don't -- I
16 believe it's certainly possible that could happen but
17 in the opinion itself, the Board seems to link them
18 together. So what -- if you could help me by pointing
19 me to the Board's opinion and say, well, this is
20 exactly where they went wrong. Not like in the
21 abstract, we think they went wrong --

22 MR. TRELA: Well --

23 HON. MOORE: -- but this is where they
24 went wrong.

25 MR. TRELA: Okay, Judge Moore. Let

1 me -- the section you were just looking at -- let's
2 look at Appendix pages 369 to 370. And where the --
3 what the Board is saying there -- let me get my hand
4 on the right -- it's talking about, at the bottom of
5 369, it's talking about the purpose of administering
6 prednisone to deal with side effects. And then it
7 says, "This" -- at the bottom -- "This literature's
8 discussion acknowledges the previously known roles of
9 abiraterone acetate and prednisone, and the discussion
10 of a corticosteroid generally contradicts the specific
11 anti-cancer role of prednisone argued by Patent
12 Owner." Well, that's the claim construction issue
13 right there. And that's right at the heart of the
14 Court's -- I'm sorry -- the Board's analysis of
15 commercial success.

16 So that's the problem. That's an
17 example of the problem, Your Honor, where I think the
18 claim construction --

19 HON. MOORE: Could -- I'm sorry.
20 Please go ahead.

21 HON. CHEN: Okay. Your label for your
22 product doesn't say anything about prednisone serving
23 as an anti-cancer agent or as killing cancer cells.
24 It only talks -- there is some place in the label that
25 talks about how it's used to handle the side effects

1 of taking the abiraterone.

2 MR. TRELA: In the -- well, the
3 indications and usage part of the label, which is the
4 important part for these purposes, talks about the
5 common --

6 HON. CHEN: Am I misunderstanding
7 something? Is there anything anywhere in the label
8 that says that prednisone itself is killing cancer
9 cells?

10 MR. TRELA: No. I don't think there's
11 anything in the label that says that prednisone itself
12 is killing --

13 HON. CHEN: But there is something in
14 the label somewhere that says this prednisone is quite
15 handy because you can deal with reducing the side
16 effects from taking abiraterone.

17 MR. TRELA: I think that's right. But
18 what the FDA approved in the indications and usage is
19 the use of the combination to treat metastatic
20 castration resistant prostate cancer. And it is the
21 combination that was evaluated and the combination
22 that was approved for its anti-cancer effects as the
23 district court found in the infringement part of the
24 decision. The label precisely tracks the claim
25 language.

1 HON. CHEN: So can I take you back to
2 trying to understand what is an anti-cancer agent?

3 MR. TRELA: Sure.

4 HON. CHEN: In the spec, it says at
5 column 4, we term "anti-cancer agents" as "any
6 therapeutic agent that directly or indirectly kills
7 cancer cells or directly or indirectly prohibits,
8 stops or reduces the proliferation of cancer cells".

9 MR. TRELA: Yes.

10 HON. CHEN: So I think I understand
11 what "directly" means. But could you elaborate on
12 what it means to "indirectly kill cancer cells or
13 indirectly prohibits, stops or reduces the
14 proliferation of cancer cells"?

15 MR. TRELA: Sure.

16 HON. CHEN: Because I could imagine one
17 theory of "indirectly" being there's a main event
18 drug, maybe it's abiraterone, that does all the direct
19 killing, but it's not tolerable on its own for a
20 patient. And so now you need something else to handle
21 all the side effects that comes with the main event
22 drug. And that could be something like a
23 glucocorticoid that compensates for a loss of hormone
24 that comes with taking the inhibitor.

25 MR. TRELA: Right.

1 HON. CHEN: So why wouldn't that be
2 understood as perhaps indirectly assisting in the
3 treatment of cancer and killing or prohibiting the
4 promotion of further cancer cells?

5 MR. TRELA: Well, for a couple of
6 reasons, Your Honor. One is, I think there's --

7 HON. CHEN: For the broadest reasonable
8 interpretation.

9 MR. TRELA: Understood. There's
10 nothing in the specification that makes any reference
11 to any of those side effects or pain relief or
12 anything like that. So there's no suggestion that
13 that is included in the notion --

14 HON. CHEN: But I don't see anything in
15 the spec, which is not that long, in terms of going
16 through the science, right, explaining what does it
17 mean to be indirectly --

18 MR. TRELA: Well, I --

19 HON. CHEN: -- dealing with cancer.

20 MR. TRELA: I think I --

21 HON. WALLACH: There's nothing in the
22 spec unless you read "treatment" in a way different
23 than you read it.

24 MR. TRELA: Well, you have to read it
25 differently than I read it and you have to add a lot,

1 I'd suggest. But, Judge Chen, to your question -- and
2 I will say that I don't think that there's expert
3 testimony in the record on this. But I will tell you
4 what I think "directly" and "indirectly" mean here.
5 "Directly", I think, means what's called a cytotoxic
6 effect. It actually -- it's a poison for those cells
7 which is much like chemotherapy. That's the way
8 chemotherapy works.

9 "Indirect", I think means in this
10 invention cutting off the supply of hormones that
11 those cells need to survive. I think that would be an
12 indirect effect on the cancer cells or tissue. The
13 direct effect would be you directly poison them with a
14 -- for example, a chemo type agent. I think that's
15 the -- that's what that means in that context.

16 HON. MOORE: Okay. Thank you, Mr.
17 Trela. Let's hear from the collection of people on
18 the other side.

19 Mr. Krause, are you going first?

20 MR. KRAUSE: May it please the Court.
21 The USPTO is here at the Court's invitation to address
22 the questions related to the --

23 HON. CHEN: I have a logistical
24 question first. The Board issued all three IPRs in
25 the final written decision in January of 2018. The

1 patent (indiscernible) file (indiscernible) hearing
2 requests in February of 2018. For some strange reason
3 that I don't understand, and there's no earthly
4 justification I can think of of good reason the Board
5 lollygagged and took 10 full months before it issued
6 its -- the hearing decisions in December of 2018. Why
7 in the world did it take so long for the Board to
8 issue its re-hearing decision?

9 HON. MOORE: In fact, it only seemed to
10 happen after our order which they have, my guess,
11 prompted those decisions.

12 MR. KRAUSE: I honestly don't know the
13 answer to either of those questions. The Board
14 aspires to answer re-hearing requests --

15 HON. CHEN: I mean, don't you think
16 it's a little embarrassing? I mean, the Board
17 certainly was well aware that there was a concurrent
18 litigation going on. You know, it understands it
19 needs to be working with special dispatch. I mean, it
20 took about as long as it takes for a regular
21 (indiscernible) review itself to be completed for it
22 to handle a re-hearing request. It doesn't make any
23 sense.

24 MR. KRAUSE: Well, I haven't looked at
25 the underlying merits of this case. I understand it

1 is a complicated case. There might have been
2 different views within the Board panel itself. There
3 is no absolute deadline. I'm sure the Board did its
4 best to get the decision issued in a timely manner. I
5 can convey your concerns to Board management but I
6 don't have much standing here to say -- standing here
7 before you today to say to explain what happened.

8 HON. MOORE: So unlike IPRs where there
9 are certain timelines that the PTO is required to
10 comply with for completion, are you telling me there
11 is absolutely no timeline placed on the hearing
12 decisions?

13 MR. KRAUSE: There's no statutory
14 timeline. There's an aspiration --

15 HON. MOORE: Or regulatory?

16 MR. KRAUSE: I believe the trial
17 practice --

18 HON. MOORE: No. Is there a regulatory
19 timeline placement?

20 MR. KRAUSE: I don't believe there's a
21 regulatory timeline. There's a --

22 HON. MOORE: Wouldn't that seem to
23 significantly undermine Congress' goal to have an
24 expeditious and fully resolved IPR proceeding within
25 the PTO to avoid unnecessary duplicative district

1 court litigation?

2 MR. KRAUSE: I think it potentially
3 can.

4 HON. MOORE: And like in this case.

5 MR. KRAUSE: In --

6 HON. MOORE: Don't you think it did in
7 this case?

8 MR. KRAUSE: This case is extremely
9 unusual for --

10 HON. MOORE: No. Do you think it did
11 in this case?

12 MR. KRAUSE: In this case, it would
13 have been better if they had issued it sooner and we
14 could have gotten the invalidity arguments before this
15 Court --

16 HON. MOORE: And it would have
17 avoided --

18 MR. KRAUSE: -- sooner.

19 HON. MOORE: -- a lot of unnecessary
20 litigation and briefing, right?

21 MR. KRAUSE: I believe that's correct.

22 HON. MOORE: And how long did it take
23 for the Board to resolve the entire underlying IPR in
24 this case?

25 MR. KRAUSE: There were issues in this

1 case involving joinder of multiple parties as the
2 right complex case arising out of a Hatch-Waxman
3 dispute. In the joinder situation, the deadlines also
4 are off. So again, it took longer than usual. That's
5 why this is a very unusual case for resolving or even
6 for evaluating the estoppel issue.

7 HON. CHEN: What made the re-hearing
8 request so unusual?

9 MR. KRAUSE: I --

10 HON. MOORE: The opinion certainly
11 doesn't give any indication that anybody was
12 struggling with anything.

13 MR. KRAUSE: I only know from the fact
14 that it took a long time that something must have been
15 going on.

16 HON. MOORE: Do you know how long it
17 normally takes for panels? Are you aware within the
18 Agency how long it normally takes for panels to deal
19 with re-hearing requests?

20 MR. KRAUSE: I believe normally it
21 takes in the time frame of the aspirational two
22 months. Re-hearing requests often are just a check on
23 the Board to make sure that they didn't overlook
24 something or misapprehend the law. And they can
25 normally get them done in a timely manner. I don't

1 know what happened in this case.

2 HON. CHEN: Is it your sense that 10
3 months is an outlier for the Board?

4 MR. KRAUSE: That would be my --

5 HON. CHEN: Or -- I'm trying to
6 understand how meaningful is this so-called
7 aspirational goal of yours to respond to a re-hearing
8 request in one month or two months.

9 MR. KRAUSE: I'm not aware of
10 statistics on the time to re-hearing so I'd rather not
11 speculate on that. But my basic belief from seeing
12 re-hearing requests is that they're done reasonably
13 promptly.

14 HON. MOORE: I mean, I just -- I don't
15 -- I share Judge Chen's concern which when a panel is
16 aware of a concurrent district court ongoing
17 litigation, why they wouldn't promptly turn to that
18 particular re-hearing request. Not all IPRs and
19 re-hearings have concurrent district court
20 litigations. But here there was one that the panel
21 board were clearly aware of. I'm baffled.

22 MR. KRAUSE: Your Honor, it seems like
23 a fair point and I will take it back to Board
24 management.

25 HON. CHEN: Board management, yes.

1 HON. MOORE: Okay. Is there something
2 you'd like to address? Since your time ran out but
3 I'm willing to give you a chance to address something
4 if you'd like to say something.

5 MR. KRAUSE: I'm here at the Court's
6 invitation. I heard several --

7 HON. WALLACH: Now you know why.

8 HON. MOORE: In the future, you might
9 want to think twice about accepting those invitations.

10 MR. KRAUSE: Well, I was very
11 interested in the issues that were -- that we were
12 asked to respond to and I'm happy to respond to those.
13 I'm not going to presume to tell the Court how to deal
14 with the avoidance doctrines. I understand the
15 exchange that you had with Mr. Trela before me. But I
16 -- we do think the estoppel provisions are important.
17 There is some uncertainty about them. The bar at
18 large patentees/petitioners could benefit from getting
19 this Court's views on estoppel. And I guess I'll say,
20 just in broad terms, I'm not sure how far we'll go
21 with this, but the plain language is very clear on
22 both of the issues that -- the two primary issues we
23 addressed, the successful petitioner issue and the
24 final written decision issued.

25 And the arguments on the other side are

1 almost all policy arguments. And those are, I would
2 say, really are all policy arguments. And those
3 arguments --

4 HON. CHEN: Do you think those
5 policy --

6 MR. KRAUSE: -- really should be
7 addressed --

8 HON. CHEN: Do you those policy
9 arguments make sense?

10 MR. KRAUSE: I --

11 HON. CHEN: Do you think this is a
12 common sense outcome what you're advocating for in
13 terms of your conception of the statute?

14 MR. KRAUSE: Yes. Ours is a very
15 common sense outcome. The policy argument --

16 HON. CHEN: No, no. The outcome here
17 to block the defendants from persisting with its very
18 same invalidity arguments it prevailed on in front of
19 the Board three different ways?

20 MR. KRAUSE: It's perfectly consistent
21 with Congress' intent to avoid duplicative litigation.
22 Once there is --

23 HON. CHEN: But now the petitioners
24 have been deprived of their ability to pursue a
25 position that they actually prevailed on. It's not

1 that they lost but they won. So to me -- you know,
2 you say it's common sense. But to me, I would think
3 common sense goes the other way. So can you explain
4 to me why --

5 MR. KRAUSE: I mean --

6 HON. CHEN: -- it's common sense to
7 deprive and take away from the defendants a position
8 that they prevailed on in another tribunal?

9 MR. KRAUSE: It has to do with the very
10 fact that there are two tribunals at issue here. The
11 petitioner here chose to get the faster less expensive
12 more expert tribunal, the --

13 HON. CHEN: Yeah. Look where that got
14 them --

15 MR. KRAUSE: -- PTAB --

16 HON. CHEN: -- in your view.

17 MR. KRAUSE: No, no. Petitioner was
18 successful. And in the normal case --

19 HON. CHEN: Successful but in -- again,
20 you know, you extend out the logic of the current
21 track pattern. They would be enjoined from
22 commercially marketing their product under your
23 understanding of the statute.

24 MR. KRAUSE: But they -- but not at
25 all. As Your Honor suggested, the district court

1 could very easily have addressed -- have issued a stay
2 in this case and any other case where this might
3 arise. And that probably is the best result. Those
4 were the policy arguments should be addressed. If you
5 think -- if the petitioner thinks there's a bad result
6 here, they can explain that in the district court and
7 the district court more than likely would issue a
8 stay. The other place a petitioner can go if they
9 have a problem with this -- and I think it may only
10 occur in Hatch-Waxman and shouldn't even occur
11 there -- would be to go to Congress which is equipped
12 to deal with the balance between --

13 HON. MOORE: I don't know. I felt like
14 this case was a bit of the perfect storm in my mind.
15 And what I mean by that is I don't see how this
16 situation presents itself hardly ever because I feel
17 like most district courts would issue stays in
18 circumstances like this which moots this issue. I
19 also feel like the PTO usually acts quite
20 expeditiously and there aren't -- I mean, how many
21 petitions for a re-hearing are generally filed within
22 the PTO other than for simply delay tactics
23 potentially? You can't speculate on whether they're
24 for delay tactics. How many re-hearing petitions are
25 filed within the PTO?

1 MR. KRAUSE: I don't have an answer to
2 that. I think there is a standard that must be met.
3 They have to make an argument that the panel actually
4 overlooked something or misapprehended some point of
5 law. So it is --

6 HON. MOORE: You don't have any sense?
7 You can't tell me in your experience less than half or
8 less than 20 percent or -- I'll tell you right now.
9 Re-hearing petitions in the Federal Circuit, every
10 case. Every single one.

11 MR. KRAUSE: Okay.

12 HON. MOORE: So what -- you know,
13 what's your sense?

14 MR. KRAUSE: I guess in the range of
15 half, I think. But it's a guess. I'd have to check
16 with the Board to --

17 HON. MOORE: The reason -- I'm trying
18 to wrap my brain around Mr. Trela's argument that
19 there's a real problem here and that we need to reach
20 the statutory interpretation issue. Otherwise,
21 there's going to be real impact on real people out
22 there. And I was suspicious of the correctness of
23 those assertions both because the district court could
24 easily grant a stay which would obviate this problem
25 in its entirety and probably should have. And, of

1 course, the refusal to grant a stay in that case could
2 have even been mandamus to us, right? And so we could
3 do something, if necessary, as we have in the past in
4 circumstances like that.

5 But in any event, the stay was a very
6 real possibility. And the other thing is, I just
7 don't see how often it's going to be the case that the
8 PTO drags its feet as long as it did in this
9 particular set of circumstances such that we end up in
10 the situation that we're in because normally these
11 IPRs move a lot quicker. And so what I was trying to
12 gauge from you is the only open-ended avenue that I
13 was aware of was a re-hearing where there's no actual
14 time limit. And so I was trying to gauge -- I'm
15 trying to gauge -- get a sense of how real is this
16 problem that Mr. Trela has in this case.

17 MR. KRAUSE: I agree with you that it's
18 not very real because even if there have been delays
19 in re-hearing decisions, this issue has not presented
20 itself before. We haven't encountered it before this
21 case. The AIA's been in place for six or seven years
22 now. So I don't think it's a common problem. I do
23 think litigants, especially on the Hatch-Waxman side
24 and the litigants could end up -- filers could benefit
25 from understanding what the rule is. If the rule says

1 we say that might be a motivation for them to file
2 their (indiscernible) a little bit earlier -- but
3 again, that may well be beyond the scope of what this
4 Court needs to rule on here.

5 HON. CHEN: To file their
6 (indiscernible) a bit earlier or to file their IPRs a
7 bit earlier?

8 MR. KRAUSE: I'm sorry. That's what I
9 meant, to file the IPRs a little bit -- as soon as
10 possible so as to get the result contemporaneously
11 with the litigation.

12 HON. MOORE: Okay. Thank you, Mr.
13 Krause. Let's hear from Mr. Kelley.

14 MR. KELLEY: May it please the Court.
15 Good morning, Your Honors.

16 As the Court is aware, and from the
17 discussions today, we've all seen there's a lot of
18 different ways that this case can be resolved. And
19 I'm happy that Mr. Trela conceded --

20 HON. CHEN: Just a quick question. Did
21 you side file a motion to stay the district court
22 action once the IPR decisions came out last January
23 2018?

24 MR. KELLEY: No, Your Honor. Neither
25 side filed such a motion.

1 HON. CHEN: Okay. How come? I would
2 think it would have been the right instinct for your
3 side to try to stay the district court action and then
4 let the IPRs play themselves out through re-hearing
5 and then Federal Circuit appeal.

6 MR. KELLEY: Well, Your Honor, the
7 motion in limine was raised early and resolved early
8 by the district court during the hearing, actually, I
9 believe. And so it was not in our interest to stay
10 that case because we actually wanted to get to a
11 resolution of that case because we have a very, very
12 strong invalidity case. We wanted to get to the
13 issue.

14 As to whether or not a stay would have
15 theoretically worked for either side, I'm not sure it
16 would have in this case because at the time it came up
17 in the district court, the Hatch-Waxman 30-month stay
18 was in existence at that point. And the 30-month stay
19 can be adjusted, either lengthened or shortened, based
20 on the parties' activities in the case. So if one
21 side wants to slow down the case, the district court
22 can theoretically extend the 30-month stay. And if
23 the other side wants to do something the other way,
24 the district court can theoretically slow down the
25 30-month stay. So you have the background issue of

1 the 30-month stay in effect at the time this was
2 happening at the district court. And that 30-month
3 stay expired right about the time the district court
4 issued its decision in this case, I think in October
5 of 2018.

6 HON. CHEN: Okay. So you saw a risk
7 that the 30-month stay might get extended to, I don't
8 know, a 40-month stay --

9 MR. KELLEY: No, Your Honor. I didn't
10 mean to suggest that we didn't do it because we saw a
11 risk. We liked what was happening in the district
12 court. We -- I suppose we could have asked for a stay
13 but we had a very strong case. We realized that by
14 raising this issue in the district court we were
15 putting ourselves at risk a little bit. They could
16 have theoretically won at the district court. And if
17 they won on the invalidity issue at the district
18 court, there would be a stay in place right now. And
19 that stay would last as long as they can slow down the
20 PTAB cases which they've already proven their ability
21 to do quite well.

22 And so, what we wanted to do is get to
23 the end of the case so that we could go on to the
24 market. That was --

25 HON. WALLACH: What was your

1 expectation based on past experience on the amount of
2 time a re-hearing would take?

3 MR. KELLEY: I have no idea why this
4 re-hearing decision took this long. I'm aware of
5 re-hearing decisions taking in fact much longer than
6 this. On remand, I've heard of cases extending a long
7 time. But I trust that this is an outlier and I
8 believe it to be an outlier. But that doesn't mean
9 that we should just trust that there won't be an
10 outlier in the next case.

11 And incidentally, as to the amount of
12 re-hearing requests, my sense is that it's well below
13 50 percent, not that it's --

14 HON. MOORE: Like Solicitor Day at the
15 PTO. I just realized we've got three of you involved
16 in this, one on each side and one on the bench.

17 MR. KELLEY: I apologize for that.

18 HON. MOORE: I mean, we got to get it
19 right. Right? Have three solicitors weighing in.

20 MR. KELLEY: And at least two of us
21 disagree. At least two of us.

22 So before -- I want to just address one
23 issue quickly before I let it slip away. Mr. Trela
24 referred to the secondary considerations. And this is
25 as far as I can tell, the only argument as to how a

1 different claim construction could possibly matter to
2 the PTAB cases because we know it can't matter because
3 we have the Wockhardt IPR where the Board specifically
4 made findings about the teachings of Sartor --

5 HON. MOORE: Unless he's right -- which
6 I'm hoping he'll maybe readdress on rebuttal. Unless
7 he's right that there was some impact on the secondary
8 consideration evidence. I mean, that would be the
9 only thing -- you know, yeah. I will tell you. I
10 read the Wockhardt exactly that way. I turned him
11 right to the pages of it. And I read it as creating
12 an independent basis for affirming this IPR decision
13 regardless of claim construction.

14 But unless -- and his response to me
15 was not so much that I was wrong in how I read it. It
16 was more that, yes, but if they're so right about
17 claim construction, he believes that the secondary
18 consideration determinations were impacted by claim
19 construction.

20 MR. KELLEY: Right. So I understood
21 that to be his argument today as well which is that if
22 the claim construction is somehow constricted or
23 narrowed beyond what the Board found that they need a
24 do-over --

25 HON. MOORE: No. Beyond --

1 MR. KELLEY: -- on --

2 HON. MOORE: No. Beyond -- if the
3 claim construction is not what he's arguing today, it
4 should be.

5 MR. KELLEY: Oh, right. I guess that's
6 what I meant to say. The Board construed the claims
7 under BRI to a certain extent. And they are now
8 arguing that it needs to be narrower.

9 HON. MOORE: Yeah.

10 MR. KELLEY: That "treating" needs to
11 be anti-cancer treating only.

12 HON. MOORE: Right. Yeah.

13 MR. KELLEY: And that because it's
14 narrower, that affects the case. And we know it
15 doesn't affect the principal case because we have the
16 Wockhardt IPR. Okay? So then we get into secondary
17 consideration. So the question is does the anti-
18 cancer treatment requirement that they want to write
19 into that claim, does it affect the secondary
20 considerations to the extent that we need a do-over.
21 And what he pointed you to today and what I'd like to
22 address just really quickly is the language at the top
23 of page 370. And this is the sentence that actually
24 begins on 369 where it says -- the Board says "This
25 literature discussion" --

1 HON. MOORE: Give me one second. Just
2 give us a second here.

3 MR. KELLEY: Oh, I'm sorry.

4 HON. MOORE: Give a sec.

5 MR. KELLEY: I'm sorry.

6 HON. MOORE: Okay. Go ahead.

7 MR. KELLEY: So at the bottom of 369,
8 the Board writes, "This literature's discussion
9 acknowledges the previously known roles of abiraterone
10 acetate and prednisone, and the discussion of a
11 corticosteroid generally contradicts the specific
12 anti-cancer role of prednisone argued by Patent
13 Owner."

14 So what that shows us is that the board
15 was not just thinking about this anti-cancer
16 alternative in the principal part of the 103 but had
17 still had it on its mind when it got into the
18 secondary considerations. So the very sentence he
19 pointed us to demonstrates that the Board was actually
20 thinking about the anti-cancer notion of prednisone
21 that they're arguing. And so it --

22 HON. CHEN: But can you translate what
23 this statement means, "the discussion of the
24 corticosteroid generally contradicts the specific
25 anti-cancer role of prednisone argued by the Patent

1 Owner"?

2 MR. KELLEY: Sure.

3 HON. CHEN: I mean, that's the -- it
4 acknowledges the patent owner's argument of the anti-
5 cancer role of prednisone. But I don't quite -- can
6 you explain what the sentence means?

7 MR. KELLEY: I think what they're
8 getting at there is that Janssen had made an argument
9 about commercial success, that because we have
10 commercial success, this defeats the logic behind the
11 obviousness case. So it's a standard commercial
12 success approach. And there's two answers to that.
13 The first is the blocking patent which is actually the
14 more powerful answer. But the second answer is that
15 what they attribute the success to is defeated by the
16 fact that the prior art, if there was success, already
17 understood the need for a glucocorticoid like
18 prednisone in this treatment method. And because the
19 prior art already understood that, that any success
20 that they had might have been coming from that use of
21 prednisone even though --

22 HON. CHEN: And they understood that
23 from Sartor or understood that just generally to
24 reduce side effects?

25 MR. KELLEY: Understood that from

1 evidence other than Sartor because Sartor teaches us
2 about the anti-cancer effects.

3 HON. CHEN: Right.

4 MR. KELLEY: And so what the Board is
5 saying here is, look, even if you have commercial
6 success, it's not clear that the commercial success is
7 from the anti-cancer effects which you are now arguing
8 but, in fact, it's from the known palliative effects
9 that the prior art talked about in a lot of different
10 ways. That's my understanding of what the Board is
11 saying here which is just another piece of evidence
12 that the secondary consideration issues, just like the
13 main 103 issue, does not need a remand even if this
14 Court should disagree with the Board's claim
15 construction.

16 HON. WALLACH: But it also goes back to
17 the meaning of "treatment".

18 MR. KELLEY: It does, Your Honor. And
19 so, I'd like to address that right now, I guess,
20 because, Judge Chen, you raised this morning the issue
21 about an anti-cancer agent or antibiotic.

22 HON. CHEN: Or a steroid.

23 MR. KELLEY: I'm sorry. Or a steroid.
24 And that's exactly how the Board looked at this case.
25 The Board said, well, it's clearly not directed to the

1 second agent being an anti-cancer agent because it
2 presents it in the alternative.

3 But there's another rationale that we
4 can rely on. And that's in column 4 of the patent.
5 In column 4 of the patent, it discusses the need -- or
6 what refractory cancer means. And it says,
7 "refractory cancer...[is a] cancer that is not
8 responding to an anti-cancer treatment". They
9 specifically -- the inventor specifically narrowed
10 what the meant by treatment in that column of the
11 patent to a particular type of treatment, and that's
12 anti-cancer treatment. And I can point the Court
13 directly to that. That's on column 4, which is in the
14 record, at page 759. And the paragraph that begins at
15 line 23 says: "As used herein and unless otherwise
16 defined the phrase 'refractory cancer' means cancer
17 that is not responding to an anti-cancer treatment".

18 So when the inventors wanted to talk
19 about a type of treatment that was anti-cancer, they
20 knew how to say it. Just as when they wanted to talk
21 about an ingredient in their drug that was
22 specifically anti-cancer versus a steroid. They knew
23 how to do it. So the Board was on very solid ground
24 when they said "treating in the '438 patent extends
25 beyond anti-cancer treatment".

1 And so if the Court has no more
2 questions on that, I'll just turn to 315(e)(2) which,
3 as the Court understands, I think, pretty clearly, it
4 does not need to be reached in this case.

5 HON. CHEN: Before we go on the
6 Wockhardt IPR, I did see in a couple places in the
7 blue brief, I guess under the reasonable expectation
8 of success section, where they do talk about Sartor
9 and how maybe Sartor doesn't -- isn't clear enough or
10 clean enough in giving one a motivation to add
11 prednisone for some kind of anti-cancer effect. And
12 so, could you just respond to that?

13 MR. KELLEY: Sure. And I think what
14 they pointed to is the parts of the brief Your Honor
15 is looking at is testimony perhaps in the declarations
16 that they think suggest that people skilled in the
17 prior art would not have believed that Sartor -- or I
18 should say that prednisone has an anti-cancer effect.
19 So what they're doing there is they're pointing to
20 evidence that they say is contradictory.

21 And my response to that would be there
22 may have been evidence that they perceive to be
23 contradictory and it may or may not have been
24 contradictory but that was all before the Board. The
25 Board saw the evidence that they pointed to the Board

1 and the Board saw Sartor and the Board made a finding.
2 And the Board's finding was that it was recognized in
3 the art that prednisone had an anti-cancer effect.
4 And that finding is supported by substantial evidence.
5 And that substantial evidence is Sartor.

6 So the fact that they want to suggest
7 that this Court should re-weigh the evidence, we don't
8 think is persuasive. And at pages 350, 351 and I
9 think all the way to 359, that is the Board's
10 discussion of reasonable expectation of success in the
11 Wockhardt IPR. And the Board doesn't just talk about
12 it at the beginning of that. It talks about it at the
13 end. So throughout that discussion of what
14 (indiscernible) would have expected, the Board is
15 alternatively pointing to Sartor's teaching. So even
16 if this Court would somehow conclude that the BRI, the
17 broadest reasonable interpretation that the Board
18 reached should somehow have been narrower
19 notwithstanding what it says pretty clearly in the
20 specification, it still doesn't matter. It still
21 doesn't matter because the one place where they
22 brought it up -- and we would say that they've
23 actually -- they've waived that issue because of the
24 Amerigen IPR. The one place they brought it up, the
25 Board actually addressed it.

1 HON. CHEN: Is there any evidence in
2 the record that anyone was actually discouraged by the
3 so-called blocking patent from investigating how to
4 use abiraterone?

5 MR. KELLEY: I guess if the Court is
6 asking is there affirmative evidence that someone was
7 dying to conduct these studies and they said, well,
8 you know, we just can't because of this blocking
9 patent, I'm not aware of evidence like that. I think
10 the problem is we have the blocking patent. So we
11 have the exclusive right. And we have the fact that
12 no one did it. And so based on the blocking patent
13 and this Court's case law about it, that's enough to
14 suggest, well, there was an impediment. We would not
15 have done it -- and by the way, that wasn't just a
16 blocking patent but there's also the approval that
17 they had.

18 HON. CHEN: The FDA approval?

19 MR. KELLEY: Uh-huh. So -- and their
20 response to the blocking patent is that they may have
21 tried to license it. But the fact that they could not
22 entice someone to pay whatever they were seeking in
23 their royalty rate to get someone to do these
24 experiments does not overcome the fact that why would
25 someone pursue a treatment alternative that they

1 absolutely couldn't engage in because it's blocked by
2 a patent? The patent -- we don't have to wrestle with
3 the scope of the claims in that earlier patent and
4 whether it might have blocked or might not have
5 blocked. It was blocking abiraterone. That was the
6 purpose of that patent. So no one could enter the
7 field by combining abiraterone with anything else.

8 HON. CHEN: But I'm just trying to
9 understand the state of the case law. The case law
10 doesn't say that the existence of a blocking patent,
11 per se, neutralizes commercial success evidence,
12 right?

13 MR. KELLEY: Not necessarily, Your
14 Honor, but I think that where case law has gone is it
15 depends on what is actually blocked and how many
16 patents there are. I would submit that this case is a
17 little bit different because we have one ingredient
18 that we can identify by its chemical structure. And
19 that chemical structure is exactly what's the contents
20 of the exclusive right in the blocking patent. So
21 someone just -- they just simply can't get there. And
22 whatever evidence that they have about licensing, that
23 is evidence that the district court considered.
24 That's evidence that the Board looked at.

25 HON. MOORE: I'd love to see you turn

1 to 315 if you don't mind.

2 MR. KELLEY: I'd be happy to.

3 So let me start with where the
4 government and Janssen have basically put all their
5 eggs in the basket of saying this is a venue selection
6 provision. If the purpose --

7 HON. MOORE: Well, I don't care what
8 they -- how they label it. Why is the plain language
9 of this you may not assert either a civil
10 litigation -- action arising in whole or in part under
11 1538? Why -- I don't understand. I mean, the
12 language seems really clear. You can't assert any
13 ground Petitioner raised or reasonably could have
14 raised during the IPR. I don't know. That language
15 seems really plain on its face.

16 MR. KELLEY: And, Your Honor, it comes
17 under the heading of "Estoppel". And we know that
18 other portions of Title 35 or at least one other
19 portion of Title 35 refers to the estoppel that's
20 created by 315(e)(2). So we believe, as we briefed,
21 that the word "estoppel" carries with it the meaning
22 of estoppel. And so you have to interpret those words
23 in the overall scheme as to what estoppel is actually
24 being created. And --

25 HON. MOORE: No. I --

1 MR. KELLEY: I'll keep going. I just
2 want to --

3 HON. MOORE: I don't --

4 MR. KELLEY: I just want to recognize
5 it.

6 HON. MOORE: Yeah. I don't understand.

7 MR. KELLEY: Okay.

8 HON. MOORE: You just keep saying the
9 word "estoppel" over and over as though that answers
10 my question. I don't get it.

11 MR. KELLEY: Because, Your Honor, if
12 it's an estoppel provision, you have to consider how
13 it's actually creating the estoppel.

14 HON. WALLACH: Because it's grounded in
15 equity.

16 MR. KELLEY: Right. It's -- well, it's
17 grounded -- we bring with it the baggage of estoppel
18 as it's used in the district courts and as it's used
19 in equity and where it has come from. And we also
20 look at how the words that Your Honor is looking at
21 actually come from the statute.

22 HON. WALLACH: We merge law and equity
23 in these courts. So the consequence, because it's
24 grounded in equity, what you're saying is when the
25 word is used, it must necessarily imply its history.

1 MR. KELLEY: Imply its history and also
2 how we should view the rest of the words in that
3 section. And so if I will embrace for a second their
4 understanding of the words in the section and I think
5 the understanding that the Court was pointing to and
6 explain why it is that that doesn't actually make
7 their -- make any estoppel actually arise. If we
8 lost, if the petitioner lost at the Board, the reason
9 the words of 315(e)(2) create estoppel is because of
10 the overlay of the presumption of validity in the
11 district court. If our hands are tied, we turn to the
12 district court, we cannot raise what we just lost at
13 the Board over, then we lose at the district court.
14 And the reason we lose at the district court is the
15 presumption of validity kicks in and that patent is
16 invalid -- I'm sorry -- valid. If you -- not invalid,
17 I should say. If you flip it upside down, so if we
18 were to have won at the PTAB, as we did, if our hands
19 are tied, that does not create any estoppel. And
20 whatever happens in that case -- if they want to say,
21 as the government did, well, it does at the end of the
22 day -- at the end of the day it does, because at the
23 end of the day, if this Court affirms, a certificate
24 issues, those claims will essentially evaporate and
25 the co-pending district court case will go away.

1 HON. MOORE: The problem I have --

2 MR. KELLEY: That happens later.

3 HON. MOORE: One of the problems that I
4 have with your argument is I'm not sure how it makes
5 sense because you're saying, well, estoppel isn't just
6 -- it doesn't apply to all arguments you raised. It
7 only applies to all arguments you raised and lost on.
8 Right? That's your argument.

9 MR. KELLEY: No. Our argument, Your
10 Honor, respectfully, is that the estoppel of 315(e)(2)
11 doesn't in any logical sense ever apply to anything
12 someone raised or could have raised or anything if
13 they're the winner. It just doesn't apply to them
14 because that's now how estoppel works. There is --
15 when you go into court and you win on an issue, that
16 doesn't create any estoppel for you in a classical
17 sense, in a logical sense. If the government would
18 say I think (indiscernible) intuitive sense. The fact
19 that you won, you're not -- if you're just trying to
20 apply
21 it -- and we weren't even trying to do that.

22 HON. CHEN: Mr. Kelley, what if
23 Congress did intend to make it a choice of venue
24 provision? What other words would it have used other
25 than the words that it used?

1 MR. KELLEY: It would have used words
2 that clearly cut off the district court litigation so
3 as to avoid duplicative tribunals. And what they
4 would have done, first of all, is they wouldn't have
5 triggered it by the final written decision. They
6 would have triggered estoppel by the institution
7 decision because the only reason we need to know that
8 there's a final written decision in order to apply
9 estoppel, frankly, is we need to know who won or lost.

10 HON. CHEN: So --

11 MR. KELLEY: -- because that's --

12 HON. CHEN: -- if the statute said if
13 the petitioner in IPR of a claim and a patent results
14 in an institution of that IPR request then that
15 petitioner may not assert any ground of invalidity
16 that the petitioner raised or could have raised during
17 the IPR? Is that --

18 MR. KELLEY: Something like that.

19 If --

20 HON. CHEN: To me, that doesn't really
21 move the ball, you know, whether it replaced the words
22 "final written decision" under 318(a) with
23 "institution decision" --

24 MR. KELLEY: It moves the ball
25 remarkably, Your Honor. It gets it to where they

1 think it is. So what they keep saying is once you
2 choose a path, that's your path and it cuts off the
3 litigation. That's not how 315(e)(2) works. You have
4 to walk all the way down the path under their theory
5 and get to the end of the path. And then it cuts off
6 the walk that you took on the first path. That
7 doesn't make any sense.

8 So I think what Your Honor said, if I
9 understood it, would have worked if they could have
10 said once an IPR is instituted, a district court shall
11 not consider any invalidity arguments raised in the
12 IPR or could have been raised in the IPR. That would
13 be a venue choice provision. That's not what this
14 says. It says if there's an IPR and it gets to the
15 very end and there's a final written decision then
16 this kicks in. The only thing that we know based on
17 that final written decision is who the winner is --

18 HON. MOORE: Yeah. But --

19 MR. KELLEY: -- and who the loser is.

20 HON. MOORE: -- just like you pointed
21 out that Section (e) has the header "Estoppel" and you
22 would like me to insert the word "Collateral" before
23 "estoppel" even though Congress didn't and you would
24 like me to believe that Congress embraced the common
25 law of collateral estoppel when they used the word

1 "estoppel" even though there are other kinds of
2 estoppel other than collateral estoppel, the section
3 begins at Section 315 and the title of it is called
4 "Relation to Other Proceedings or Actions". So if the
5 umbrella of all of Section 315 is delineating between
6 the relationship and articulating the relationship
7 between multiple proceedings and it's Section (a) (2)
8 is all about staying a civil action as a matter of
9 right at the IPR (indiscernible) and everything. Why
10 isn't this exactly what they are alleging it is which
11 is Congress' attempt to delineate when one case should
12 move forward and not the other or when one should move
13 forward and not the other? Why isn't pretty much most
14 of what's contained within 315 including the title of
15 the whole section and a stay of civil litigation
16 action and everything else the attempt by Congress to
17 convey quite clearly that they don't want these
18 duplicative litigations going forward? And if that's
19 how I read not just the language of 315(e) (2), which
20 is how I read the language of 315(e) (2), but even if
21 it weren't how I read it, why take it in context with
22 everything else? Wouldn't I overall look at this
23 provision as one in which Congress was attempting to
24 make clear we don't want these duplicative
25 litigations?

1 MR. KELLEY: Because the statute is
2 more complicated than that. Because there are a
3 number of paragraphs --

4 HON. MOORE: You want me to look at the
5 word "estoppel" in (e) and you want that to dictate
6 how I understand (e) (2) but you don't want me to read
7 the language in the Title Section 315 even though this
8 is Section 315(e) (2)? You want me to read (e) and use
9 it to interpret (2) in the way you want but not 315?

10 MR. KELLEY: No, Your Honor. All of
11 315 has different provisions in it. And we recognize
12 that estoppel is related to how one proceeding affects
13 another proceeding. We're not saying it's not. But
14 to say that they're all choice of venue provisions
15 ignores the fact that Congress did actually put in
16 choice of venue provisions. If --

17 HON. MOORE: Do you agree that (a) (2)
18 is a choice of venue provision?

19 MR. KELLEY: No, Your Honor. I
20 wouldn't agree that (a) (2) is a choice --

21 HON. MOORE: So what do you think
22 (a) (2) is?

23 MR. KELLEY: (a) --

24 HON. MOORE: It says if there's a civil
25 action that was filed after an IPR, civil action shall

1 be automatically stayed. And it gives a number of
2 exceptions but why isn't that --

3 MR. KELLEY: Right. Well, because --

4 HON. MOORE: -- a clear indication by
5 Congress that it intends only one to move forward at a
6 time and not both to move forward simultaneously?

7 MR. KELLEY: So if -- so if the
8 mandatory stay provision is actually triggered and not
9 overcome by any of those other things, then, yes, that
10 would be compelling the district court to stop and the
11 PTAB moving forward. And then 315(a)(1), if the DJ
12 action is filed first that would bar the inter partes
13 review. Those are choice of venue provisions. And
14 then if we skip down to --

15 HON. MOORE: You mean DJ? You said DJ.
16 I don't --

17 MR. KELLEY: Yes. If --

18 HON. MOORE: Oh. Oh, okay.

19 MR. KELLEY: Yes. That's right.
20 That's what that means. "An inter partes review may
21 not be instituted if, before the" --

22 HON. MOORE: Yep. Yep.

23 MR. KELLEY: Okay.

24 HON. MOORE: I get it now.

25 MR. KELLEY: So then we get down to

1 315(b). 315(b) is where we get the one-year bar from.
2 So we know that if you are a defendant and you're
3 sued, under 315(b), you can't move forward after one
4 year. And so those are where Congress is saying this
5 can happen or that can happen. Those are the choice
6 of venue provisions. 315(e)(2) is simply not a choice
7 of venue provision. It's not telling you that
8 district court, you have to stop. Once we know that
9 PTAB is going to make a decision, there's nothing else
10 for the district court to do.

11 HON. MOORE: Is there anything else you
12 wanted to address? I understand your arguments on
13 this. Is there anything else that you think we need
14 to hear about before we let Mr. Trela get up and have
15 his rebuttal time?

16 MR. KELLEY: No.

17 HON. MOORE: Excellent. Thank you.

18 MR. KELLEY: Thank you, Your Honor.

19 HON. MOORE: Go ahead, Mr. Trela.

20 We'll give you like your whole five minutes of
21 rebuttal time. I hope you don't have to use all of
22 it.

23 MR. TRELA: Well, I will try not to,
24 Your Honor, but I can't make any promises, I'm afraid.

25 HON. WALLACH: We won't let you run

1 over them.

2 HON. MOORE: Oh yeah.

3 MR. TRELA: Well, let me pick up with
4 315(e)(2) really briefly. A couple of things on that.

5 One is, as I think Your Honor pointed
6 out, the heading that they're relying on -- first of
7 all, you only look at headings if there's ambiguity.
8 The law is very clear on that. The heading they're
9 relying on is estoppel not collateral estoppel which
10 is the way they want the Court to read it.

11 The other thing that they completely
12 ignore is the predecessor statute which said exactly
13 what they want this one to say. And Congress changed
14 it. Change is presumed to have meaning.

15 The other thing is that the argument --

16 HON. WALLACH: That's like Sutherland
17 on statutory can stretch? Legislature also presumed
18 to have common sense.

19 HON. MOORE: If you cite that, do you
20 have to do it with a southern accent? Is that part of
21 --

22 MR. TRELA: Sutherland is from the
23 south, I think.

24 HON. MOORE: Okay.

25 MR. TRELA: Well, Your Honor, I don't

1 know if there's a presumption about common sense.

2 There is a presumption --

3 HON. WALLACH: Yes, there is in
4 Sutherland.

5 MR. TRELA: -- that the plain language
6 of the statute should be applied. And the plain
7 language here is pretty clear.

8 The other thing is the --

9 HON. WALLACH: It says in Sutherland
10 the legislature is presumed to have a rational
11 purpose.

12 MR. TRELA: True. And there is a
13 rational purpose here. Once the Agency's deciding an
14 issue, Courts shouldn't get into it. And that gets to
15 the institution decision point. And I'm not
16 completely sure I followed that but under 317(a), the
17 fact that an institution decision was made doesn't
18 inevitably mean that a final written decision is going
19 to follow. So you need the final written decision.
20 And it's not just because -- it's not because you need
21 to know who won. It's because you need to know is the
22 Agency going to decide validity.

23 Now on the Wockhardt alternative claim
24 construction point, first, Judge Moore, to answer your
25 question, our opening brief, pages 37 to 38, reply

1 pages 10 to 11, we do, in fact, address that. And our
2 argument on that is not limited just to objective
3 indicia. It also goes to reasonable expectation of
4 success. The Board, although it said that Sartor --
5 the 1998 Sartor reference might have led one of
6 ordinary skill to expect that prednisone would have an
7 anti-cancer effect, the Board never found that one of
8 ordinary skill would reasonably expect the combination
9 -- that prednisone in the combination would have an
10 anti-cancer effect along with abiraterone. And, in
11 fact, it could not have made that finding because the
12 petitioners told the Board it couldn't make that
13 finding.

14 Just as an example, in the Amerigen
15 petition -- and this is at 29,303 of the Appendix --
16 it told the Board in the 1980s, there was a belief
17 that prednisone might be useful for treating prostate
18 cancer. But by 2006, it was known that prednisone was
19 not effective as an anti-cancer agent. They say the
20 same thing at 29,342. And each of the petitioners'
21 experts took the position that one of ordinary skill
22 would not have expected that prednisone in the
23 combination in 2006 to have an anti-cancer effect. We
24 cite that in our blue brief at pages 38 to 39 and we
25 quote some of them. But if you look at those

1 references in the Appendix, they're very clear on
2 that. There was no expectation of success in
3 achieving these claims with prednisone having an anti-
4 cancer effect.

5 Another thing I wanted to turn to --

6 HON. CHEN: What about the statement
7 that prednisone alone led to an average decline of 33
8 percent in PSA responses after initiating prednisone
9 for up to six months?

10 MR. TRELA: Couple of things with that.
11 And that's, I think, from Sartor 1998. By 2006, even
12 Sartor himself recognized that prednisone alone did
13 not have anti-cancer efficacy. Also, the standard for
14 looking at PSA had completely changed. Drops of 33
15 percent were not considered -- it wasn't even a
16 reportable response. You needed a response of at
17 least 50 percent of a certain duration before it was
18 even considered evidence of activity much less
19 efficacy in treating cancer.

20 So by the time -- and as Amerigen
21 recognized, early on there was this thinking that
22 prednisone might have an anti-cancer effect. But by
23 2006, that had been completely dissipated. And 2006
24 is the relevant time.

25 Now on the -- there was also a claim --

1 HON. MOORE: So you think that we need
2 to overturn the Board's fact finding related to Sartor
3 reasonably standing for the proposition that
4 administering of prednisone is tolerated and
5 effective in a subset of cancer patients?

6 MR. TRELA: No. I don't think you need
7 to overturn. I think you should but I don't think you
8 need to.

9 HON. MOORE: But you didn't argue for
10 us to. So --

11 MR. TRELA: Well, then I guess you
12 shouldn't. But that's not the finding the Board
13 needed. The finding was a reasonable expectation of
14 success and achieving the claimed invention. The
15 claimed invention is the combination with prednisone
16 having anti-cancer effect in the combination. Their
17 experts said that was not a reasonable expectation at
18 the time.

19 Now on the claim construction issue,
20 Mr. Kelley referred to column 4 and the reference to
21 anti-cancer treatment. But what he loses sight of is
22 that prednisone is expressly defined to be an anti-
23 cancer agent. So everything he said about the
24 supposed distinction between steroids and anti-cancer
25 agents, whatever it applies to, it does not apply to

1 prednisone and prednisone is what's in the claims.

2 And I'm out of time and I'm not going
3 to run over.

4 HON. MOORE: Well done. I thank all
5 counsel for their argument. It was very helpful to
6 the Court today.

7 MR. TRELA: Thank you, Your Honor.

8 THE CLERK: All rise.

9 (End of oral argument)

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C E R T I F I C A T I O N

I, Lisa Beck, certify that the foregoing transcript is
a true and accurate record of the proceedings.

/s/ Lisa Beck

Lisa Beck

Date: October 27, 2021

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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EXHIBIT 9

EXHIBIT Q

From: Melly Meadows <mellymeadows@aol.com>
Sent: Friday, September 9, 2022 1:28 AM
To: Scott Moomaw <Scott.Moomaw@liquidia.com>
Subject: Yutrepia for PAH

EXTERNAL MESSAGE

To Whom it may Concern,

I have Pulmonary Arterial Hypertension. I live in fear of the unknown and the harsh reality that I have a disease that has a deadly prognosis. I don't want to die! I want to be alive and yet I am afraid of suffocating slowly. Pause for a moment please and really think about this ... I don't know when my breath will end.

Pulmonary Arterial Hypertension (PAH) is a disease that you can not imagine how it must feel. You can't image what it is like to feel like you can't breathe! This disease is not as well understood as breast cancer or even lupus (which I also have). This diagnosis and disease process are literally like sucking the air out of a room and leaving the patient with no escape.

I was first diagnosed with PAH in November of 2006. I was newly married and wanted to have children. However, when I was diagnosed with Pulmonary Arterial Hypertension, I was told that most people with this diagnosis only live about five years. That meant I would never be a mother. I would never have a child. For five years, I stopped living and I waited to die. Every day I wondered what my death was going to be like and how intense the suffering and pain would be. Newer drugs and treatments were coming on the market and after five years, I was still alive! I realized then that I had just lost five years of life because I feared death. I had to learn how to live again and how to face life with courage. And that is what I am doing. My story is on YouTube: "Ballerina with Lupus".

There is a new drug that is proven to help treat PAH, called Yutrepia. It is more portable than the other drugs that are similar, and the dosing of the medication is more predictable and easier to adjust. However, this drug treatment is being pushed to the sideline because of patent litigation. This means that lawyers are fighting over what drug is made available and when, to people like me with a deadly disease.

Let me put this into perspective. The new drug, Yutrepia, is more convenient than the other "like" drugs and it has the potential to treat people with PAH as well as other lung diseases. There are approximately 40,000 people in the U.S. with PAH. The average three-year death rate of this disease is 21%. This means that in the three years that Yutrepia will have been caught up in litigation, 8,400 people will die from PAH. That is over eight thousand individual people who have a story like mine who will never have been given the option or the choice of a life-changing medication because of bureaucracy. I respect patent laws and intellectual property. However, when it comes down to basic life and death of people with a fatal disease, shouldn't the right to have ALL treatment options be made available? And shouldn't quality of life and healthCARE take precedence over petty litigation?

On behalf of the people with PAH, our families, and our future, I implore that you please grant approval of the drug Yutrepia. We, the patients, need treatment options because this gives us hope!

Most Sincerely,
Melly Meadows McCutcheon

EXHIBIT 10

EXHIBIT Y

From: Shirley Craig <Phnomore@att.net>

Sent: Thursday, September 8, 2022 1:47 PM

To: Scott Moomaw <Scott.Moomaw@liquidia.com>; Shirley Craig <Phnomore@att.net>

Subject: Yutrepia

EXTERNAL MESSAGE

TO WHOM THIS MAY CONCERN:

My name is Shirley Craig: I was diagnosed with Primary Pulmonary Hypertension secondary to Eisenmenger's Syndrome December 1990. There were NO medications at that time to treat it so I lived on oxygen for the next 18 years until I was able to receive a heart/lung transplant.

But after nine years, I entered a study and the medication really helped to get me to transplant. I was put on other medications along the way as they were developed. It was scary knowing there was not much out there to help me--and there still aren't compared to many diseases even today.

So, having a known medication-- **Yutrepia**--a dry powder inhaled Treprostinil that is simple, approved, and easy to use (made by Liquidia) needs to be made available to patients now.

'PHers' need every medication to be able to 'live' a quality life. We have very few and not every one works for every patient.

Respectfully,
Shirley J Craig
phnomore@att.net
832-418-1405

Houston PH Support Group Leader

EXHIBIT 11

EXHIBIT Z

From: Tracey Considine <Tracey.Considine@sphp.com>
Sent: Thursday, September 8, 2022 3:07 PM
To: Scott Moomaw <Scott.Moomaw@liquidia.com>
Subject: Yutrepia

You don't often get email from tracey.considine@sphp.com. [Learn why this is important](#)

EXTERNAL MESSAGE

Hi, my name is Tracey Considine. I am an Registered Nurse in the Albany, New York Tri-city area that has been treating pts with PH for over 20 years. I also the PH Support Group Leader in my area, and Nurse Liaison for patients. I would appreciate Yutrepia getting approved, and be available for patients, as the more treatment options available, the more it brings HOPE to these patients that are dealing with this horrible disease.

Thank You,
Tracey Considine

Confidentiality Notice:

This e-mail, including any attachments is the property of Trinity Health and is intended for the sole use of the intended recipient(s). It may contain information that is privileged and confidential. Any unauthorized review, use, disclosure, or distribution is prohibited. If you are not the intended recipient, please delete this message, and reply to the sender regarding the error in a separate email.

EXHIBIT 12

Exhibit DD

To Whom It May Concern:

Despite the approval of more than 10 novel therapies, pulmonary arterial hypertension remains a progressive and fatal condition that can lead to heart failure and death. There is no cure.

In many cases, current approved therapeutics, while effective, can be burdensome and the therapeutic window limited due to a range of issues including intolerable side effects and complex route of drug administration.

YUTREPIA™ was introduced to the pulmonary hypertension community in 2015 and was the first clinical program to explore the benefits of an inhaled dry powder formulation of treprostinil for pulmonary hypertension patients who were naïve to prostacyclin therapy or transitioning from nebulized Tyvaso.

In November 2021, the US Food & Drug Administration (FDA) issued tentative approval of YUTREPIA based on the primary endpoint of the INSPIRE trial and comparable bioavailability to Tyvaso nebulizer.

YUTREPIA, in part due to its unique PRINT formulation, is the first low-resistance dry powder inhaler to provide patients a wider and higher range of therapeutic doses that can be more easily administered in just a few breaths compared to nebulizers. We believe that YUTREPIA's profile will help build on the body of knowledge and medical literature that higher inhaled doses may lead to better clinical outcomes, quality of life, and overall survival.

Pulmonary hypertension represents a chronic and rare disease. Our patient communities rely on the FDA to approve innovative, safe, and effective treatment to reach those in need. We believe Yutrepia meets these high-quality standards and has the potential to be a critical treatment option for our patients.

Based on these key attributes, we believe Yutrepia offers an important treatment choice for providers and patients and support the recommendation for commercial availability as soon possible.

Sincerely,

Akram Khan

Akram Khan (Sep 17, 2022 14:11 PDT)

Akram Khan, MD
Associate Professor of Medicine
Division of Pulmonary and Critical Care Medicine
Oregon Health and Science University

Harrison W. Farber


Harrison W. Farber (Sep 16, 2022 12:52 EDT)

Harrison W. Farber, MD
Professor of Medicine
Director of Pulmonary Embolism Response Team
Division of Pulmonary Critical Care
Tufts Medical Center



Ali Ataya (Sep 16, 2022 12:39 EDT)

Ali Ataya, MD
Associate Professor of Medicine
University of Florida Health

 Jeremy Feldman (Sep 15, 2022 19:07 PDT)

Jeremy Feldman, MD, FCCP
Director, Pulmonary Hypertension Program
Medical Director of Research
Director, Barrow HHT Program
Arizona Pulmonary Specialists




Deborah Jo Levine MD FCCP FAST (Sep 15, 2022 20:01 PDT)

Deborah Jo Levine, MD
Pulmonary, Allergy, Critical Care
Stanford University, Stanford CA



John W. McConnell (Sep 16, 2022 13:29 EDT)

John W. McConnell, MD
Norton Medical Group
Pulmonology, Sleep Medicine



Ioana Preston, MD
Associate Professor of Medicine
Tufts University School of Medicine
Director, Pulmonary Hypertension Center
Tufts Medical Center
Boston, MA



Murali Chakinala (Sep 16, 2022 21:12 CDT)

Murali Chakinala, MD
Professor, Pulmonary and Critical Care Medicine
Director, Pulmonary Hypertension Clinic
Washington University School of Medicine



Nicholas Hill (Sep 17, 2022 08:14 EDT)

Nicholas Hill, MD
Chief of the Division of Pulmonary, Critical Care and Sleep
Tufts University School of Medicine



Sudarshan Rajagopal (Sep 15, 2022 22:41 EDT)

Sudarshan Rajagopal, MD
Associate Professor of Medicine
Duke University School of Medicine



Rajan Saggar, MD
Professor of Medicine
Director of Pulmonary Hypertension Program
Division of Pulmonary Critical Care
University of California, Los Angeles

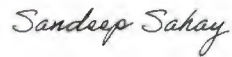


Richard Channick, MD
Professor of Medicine
Co-Director of Pulmonary Vascular Program
Division of Pulmonary Critical Care
University of California, Los Angeles



Robert P Frantz (Sep 18, 2022 11:27 GMT+1)

Robert Frantz, MD
Rochester MN



Sandeep Sahay, MD
Co-Director, Pulmonary Hypertension and CTEPH Programs,
Associate Professor,
Division of Pulmonary, Critical Care & Sleep Medicine,
Houston Methodist Hospital



Shelley Shapiro (Sep 16, 2022 17:47 PDT)

Shelley Shapiro, MD
Professor of Medicine
Director of Pulmonary Hypertension Program
Division of Pulmonary Critical Care
West Los Angeles VA Healthcare Center
University of California, Los Angeles



T.g.shah (Sep 15, 2022 22:03 CDT)

Trushil Shah, MD
Assistant Professor Of Internal Medicine
Pulmonary Hypertension Program
UT Southwestern Medical Center

EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS)
CORPORATION,)
)
Plaintiff,)
)
v.) C.A. No. 20-755 (RGA)
)
LIQUIDIA TECHNOLOGIES, INC.,)
)
Defendant.)

**PLAINTIFF UNITED THERAPEUTICS CORPORATION’S MOTION TO DISMISS
DEFENDANT’S INVALIDITY COUNTERCLAIMS AND DEFENSES**

Pursuant to Federal Rule of Civil Procedure 12(b)(6), or, alternatively under Rule 12(b)(1), Plaintiff United Therapeutics Corporation moves to dismiss Defendant Liquidia Technologies, Inc.'s counterclaim for a declaration of invalidity of U.S. Patent No. 10,716,793 and related defenses. The grounds for this motion are set forth in Plaintiff's Opening Brief and the Request for Judicial Notice, submitted herewith.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Michael J. Flynn

OF COUNSEL:

Douglas H. Carsten
Joshua Mack
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real
San Diego, CA 92130
(858) 305-2300

Jack B. Blumenfeld (#1014)
Michael J. Flynn (#5333)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mflynn@mnat.com

Attorneys for Plaintiff United Therapeutics Corporation

Adam W. Burrowbridge
WILSON SONSINI GOODRICH & ROSATI
1700 K Street NW, Fifth Floor
Washington, DC 20006
(202) 973-8800

William C. Jackson
BOIES SCHILLER FLEXNER LLP
1401 New York Avenue NW
Washington, DC 20005
(202) 237-2727

August 26, 2020

CERTIFICATE OF SERVICE

I hereby certify that on August 26, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 26, 2020, upon the following in the manner indicated:

Karen E. Keller, Esquire
Jeff Castellano, Esquire
David M. Fry, Esquire
Nathan R. Hoeschen, Esquire
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
*Attorneys for Defendant Liquidia
Technologies, Inc.*

VIA ELECTRONIC MAIL

Sanya Sukduang, Esquire
Jonathan Davies, Esquire
COOLEY LLP
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004-2400
*Attorneys for Defendant Liquidia
Technologies, Inc.*

VIA ELECTRONIC MAIL

Erik Milch, Esquire
COOLEY LLP
11951 Freedom Drive, 14th Floor
Reston, VA 20190-5640
*Attorneys for Defendant Liquidia
Technologies, Inc.*

VIA ELECTRONIC MAIL

Ivor Elrifi, Esquire
COOLEY LLP
55 Hudson Yards
New York, NY 10001-2157
*Attorneys for Defendant Liquidia
Technologies, Inc.*

VIA ELECTRONIC MAIL

Lauren Krickl, Esquire
Deepa Kannappan, Esquire
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
*Attorneys for Defendant Liquidia
Technologies, Inc.*

VIA ELECTRONIC MAIL

/s/ Michael J. Flynn

Michael J. Flynn (#5333)

EXHIBIT 14

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS
CORPORATION,
Plaintiff,

V.

LIQUIDIA TECHNOLOGIES, INC.,
Defendant.

Civil Action No. 20-cv-755-RGA

MEMORANDUM ORDER

Before me is Plaintiff's motion to dismiss Defendant's counterclaims pursuant to Rule 12(b)(6) or alternatively Rule 12(b)(1) of the Federal Rules of Civil Procedure. (D.I. 28). The motion is briefed. (D.I. 29, 37, 38). For the following reasons, Plaintiff's motion is denied.

Plaintiff United Therapeutics filed a complaint for patent infringement against Defendant Liquidia on June 4, 2020. (D.I. 1). The complaint was amended on July 22, 2020 to add infringement claims for a third patent, the newly issued U.S. Patent No. 10,716,793 (the “793 patent”). (D.I. 16). Defendant filed an answer to Plaintiff’s amended complaint with counterclaims, including counterclaim count V, which alleges invalidity of the ‘793 patent. (D.I. 23). Plaintiff filed a motion to dismiss Defendant’s counterclaim and related defenses based on assignor estoppel as one of seven named inventors of the ‘793 patent – Dr. Robert Roscigno – is (or was) “Senior Vice President, Product Development” of Defendant and therefore in privity with Defendant. (D.I. 28). He had previously assigned his interest in the patent to Plaintiff. (*Id.*).

A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to the complainant, a court concludes that those allegations “could not raise a claim of entitlement to relief” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007). “Rule 12(b)(1) allows a defendant to attack the allegations in the complaint and submit contrary evidence in its effort to show that the court lacks jurisdiction.” *Davis v. Wells Fargo*, 824 F.3d 333, 349 (Fed. Cir. 2016). However, “[t]he Supreme Court has authorized courts to dismiss under Rule 12(b)(1) for lack of jurisdiction due to merits-related defects in only narrow categories of cases . . . ‘where the alleged claim under the Constitution or federal statutes clearly appears to be immaterial . . . or where such a claim is wholly insubstantial and frivolous.’” *Id.* at 349-50 (quoting *Bell v. Hood*, 327 U.S. 678, 682–83 (1946)). The doctrine of “[a]ssignor estoppel also prevents parties in privity with an estopped assignor from challenging the validity of the patent. Whether two parties are in privity depends on the nature of their relationship in light of the alleged infringement. ‘The closer that relationship, the more the equities will favor applying the doctrine’ of assignor estoppel. Assessing a relationship for privity involves evaluation of all direct and indirect contacts.” *Mentor Graphics Corp. v. Quickturn Design Sys.*, 150 F.3d 1374, 1379 (Fed. Cir. 1998) (quoting *Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990)) (internal citations omitted).

Plaintiff asserts that Defendant’s counterclaim for a declaration of invalidity of the ‘793 patent and the related defenses should be dismissed based on assignor estoppel. (D.I. 29 at 1). Plaintiff is correct that assignor estoppel will apply to persons or entities in privity with the inventor. *See Diamond Sci. Co. v. Ambico, Inc.*, 848 F.2d 1220 (Fed. Cir. 1988). And it does not

appear that there is any contested issue about whether Dr. Roscigno made an assignment of his rights in the patent.

Determining whether privity exists, however, is more difficult. In order to apply assignor estoppel based on privity requires assessing the relationship between the inventor and the associated entity. *See Shamrock*, 903 F.2d at 793. Even accepting Plaintiff's assertions as true, it is unclear at this stage whether sufficient privity exists to apply assignor estoppel. A determination that Defendant is in privity with a named inventor of the '793 patent will require a fact intensive evaluation of their relationship and a balancing of the equities. *See Mentor Graphics*, 150 F.3d at 1379. As a result, the finding of privity required for the Court to apply assignor estoppel and dismiss Defendant's counterclaim cannot appropriately be made in the present posture, when the Court must consider the allegations in the light most favorable to the nonmoving party. *See Twombly*, 550 U.S. at 558. Further, there is no indication that the counterclaims at issue are "wholly insubstantial and frivolous" in order to warrant dismissal under Rule 12(b)(1) for lack of subject-matter jurisdiction. *Bell*, 327 U.S. at 682–83.

For the reasons set forth above, I deny Plaintiff's motion to dismiss Defendant's counterclaim.

IT IS SO ORDERED this 3rd day of November 2020.

/s/ Richard G. Andrews
United States District Judge

EXHIBIT 15

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I. INTRODUCTION

In accordance with Local Rule 16.3(c)(5) of the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Plaintiff United Therapeutics Corporation (“Plaintiff” or “UTC”) submits the following statement of contested issues of law for the action against Defendant Liquidia Technologies, Inc. (“Defendant” or “Liquidia”).

The following statements are not exhaustive, and Plaintiff reserves the right to prove any matters identified in its pleadings, discovery responses, including in its contentions, and/or expert reports and depositions. Plaintiff reserves the right to modify or amend this Exhibit to the extent necessary to reflect any future rulings by the Court, to supplement or amend this Exhibit to fairly respond to any new issues that Defendant may raise, to address any additional discovery produced by Defendant, or to address any amendments to Defendant’s NDA. To the extent Plaintiff’s issues of fact that remain to be litigated, which is submitted as Exhibit 2 hereto, contains issues of law, those issues are incorporated herein by reference. Moreover, if any issue of law identified below should properly be considered an issue of fact, then such statement should be considered to be part of Plaintiff’s statement of issues of fact that remain to be litigated.

Further, Plaintiff’s identification of the issues that remain to be litigated on issues where Defendant bears the burden of proof is based on its understanding of the arguments that Defendant has put forth to date. To the extent Defendant attempts to introduce different or additional legal arguments to meet its burden of proof, Plaintiff reserves its rights to contest those legal arguments, and to present any and all rebuttal evidence in response to those arguments, and will not be bound by this summary of remaining legal issues.

A. The Asserted Patents and Claims

1. Following UTC’s Stipulation of Partial Judgment of Non-Infringement, and for purposes of trial, the Patents-in-Suit and asserted claims are:

U.S. Patent No.	Asserted Claims
9,593,066 (“the ’066 patent”)	1, 2, 3, 6, 8, 9
10,716,793 (“the ’793 patent”)	1, 4, 6, 7, 8

B. Defendant’s Accused Infringing Product

2. The accused infringing product is that described in Defendant’s New Drug Application No. 213005 under § 505(b)(2) of the Federal Food Drug, and Cosmetic Act (the “505(b)(2) Application”) to the United States Food and Drug Administration (“FDA”) seeking approval, prior to the expiration of the ’066 and ’793 patents, to manufacture, market, and sell a version of Plaintiff’s TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml that is approved by FDA for treatment of pulmonary arterial hypertension (the “Proposed Product”).

II. INFRINGEMENT

A. Legal Standards

3. Plaintiff has the burden of proving infringement by a preponderance of the evidence. *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1314 (Fed. Cir. 2011).

4. “A patentee may prove infringement by any method of analysis that is probative of the fact of infringement, and circumstantial evidence may be sufficient[.]” *Martek BioSciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009) (citation and internal quotation marks omitted); *Liquidia Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006).

5. Under 35 U.S.C. § 271(g) a party is liable for infringement when it imports, offers to sell, sells, or uses within the United States a product which is made by a process patented in the

United States and that product is not materially changed by subsequent processes or does not become a trivial and nonessential component of another product.

1. Infringement in the Hatch-Waxman Context

6. A § 271(e)(2)(A) infringement suit differs from typical infringement suits (e.g., a § 271(a) infringement suit) in that infringement inquiries “are *hypothetical* because the allegedly infringing product has not yet been marketed.” *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003) (emphasis added); see *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) (“The relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product.”).

7. In a Hatch-Waxman Act suit, the infringement inquiry is a hypothetical inquiry because it is conducted and determined prior to any actual marketing, sale, or use of one or more generic proposed drug products based upon an analysis of the proposed generic product and administration instructions that the accused infringer is likely to sell and provide following FDA approval. *Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002).

8. To prove infringement, the patentee need only show that it is more likely than not that the proposed NDA product would, if commercially marketed, satisfy the claim limitations of at least one of the claims of the patents-in-suit. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1287 (Fed. Cir. 2010); *Abbott Labs.*, 300 F.3d at 1373.

9. In determining whether a proposed NDA product would more likely than not infringe at least one claim of at least one of the patents-in-suit, a court must consider all relevant evidence, including the NDA filing itself and other evidence provided by the parties. *Id.*

10. As to patents claiming new methods of treatment, a generic NDA applicant may still be liable for inducing infringement even though it does not directly infringe a method patent. 35 U.S.C. § 271(b).

2. Infringement Under the Doctrine of Equivalents

11. A party that makes, uses, sells, offers to sell within, or imports into the United States a product (and/or by a process) that does not literally meet all of the elements of a claim and thus does not literally infringe that claim, can still directly infringe if that product (and/or that process) satisfies the claim elements “under the doctrine of equivalents.”

12. Under the doctrine of equivalents, a product or process infringes a claim if the accused product or process contains elements or performs steps that literally meet or are equivalent to each and every element of the claim. An element or step is equivalent to an element of a claim that is not met literally if a person having ordinary skill in the field of technology of the patent would have considered the differences between them to be “insubstantial” or would have found that the structure or action: (1) performs substantially the same function and (2) works in substantially the same way (3) to achieve substantially the same result as the element of the claim. In order to prove infringement by “equivalents,” the patentee must prove the equivalency of the structure or action to the claim element by a preponderance of the evidence. Each element of a claim must be met by the accused product or process either literally or under the doctrine of equivalents for the court to find infringement.

13. Known interchangeability of the claim element and the proposed equivalent is a factor that can support a finding of infringement under the doctrine of equivalents. In order for the structure or action to be considered interchangeable, the claim element must have been known at the time of the alleged infringement to a person having ordinary skill in the field of technology of the patent.

3. Induced Infringement

14. 35 U.S.C. § 271(b) provides that “[w]hen one actively induces infringement of a patent may still be liable as an infringer.”

15. Direct infringement is a necessary predicate for a finding of induced infringement in ordinary patent infringement cases. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014).

16. Inducement liability requires that “the defendant possessed specific intent to encourage another’s infringement and not merely that the defendant had knowledge of the acts alleged to constitute infringement.” *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).

17. Circumstantial evidence can support a finding of specific intent to induce infringement. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (citing *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988)).

18. “Inducement can be found where there is ‘[e]vidence of active steps taken to encourage direct infringement,’ which can in turn be found in ‘advertising an infringing use or instructing how to engage in an infringing use.’” *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630–31 (Fed. Cir. 2015) (alteration in original) (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)).

19. When proof of specific intent depends on the label accompanying the marketing of a drug inducing infringement by physicians and patients taking the drug, “[t]he label must encourage, recommend, or promote infringement.” *Takeda*, 785 F.3d at 631.

20. The contents of the label itself may permit the inference of specific intent to encourage, recommend, or promote infringement. *Vanda Pharms. Inc. v. W.-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018) (citing *Sancfi v. Watson Labs. Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017)).

21. Induced infringement can be proven where the instructions in a proposed label

would inevitably lead at least some consumers (e.g., patients and/or their instructing physicians) to practice a claimed method of a patent. *AstraZenecaLP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

22. A patentee in a Hatch-Waxman litigation asserting method patents does not have to prove that prior use of the NDA-approved drug satisfies the limitations of the asserted claims. *See, e.g., Sanci*, 875 F.3d at 643 (affirming inducement finding where the district court found that “the inducing act will be the marketing by [ANDA applicants] of their generic dronedarone drugs with the label described” and “the induced act will be the administration of dronedarone by medical providers to patients meeting the criteria set forth in the [claims at issue]”); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1368 (Fed. Cir. 2017) (“not requir[ing] evidence regarding the general prevalence of the induced activity”); *AstraZeneca*, 633 F.3d at 1057 (affirming district court’s grant of a preliminary injunction based on claims of induced infringement where the district court found that “the proposed label would cause some users to infringe the asserted method claims”); *see also Warner-Lambert*, 316 F.3d at 1364 (“The infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed.”).

23. Accordingly, Plaintiff “can satisfy its burden to prove the predicate direct infringement by showing that if the proposed []NDA product were marketed, it would infringe the [asserted patents].” *Vanda*, 887 F.3d at 1130; *see, e.g., Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) (“The infringement determination is thus based on consideration of all relevant evidence, and because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA’s description of the drug, the ANDA itself dominates the analysis.” (alterations and internal quotation marks omitted));

AstraZeneca, 633 F.3d at 1060 (explaining that the district court “correctly determined” that language in the ANDA label “would inevitably lead some consumers to practice the claimed method”).

24. Even if the proposed generic NDA product has “substantial noninfringing uses,” the generic NDA applicant may still be liable for inducing infringement. *Vanda*, 887 F.3d at 1133 (“Section 271(b), on inducement, does not contain the ‘substantial noninfringing use’ restriction of section 271(c), on contributory infringement.” (quoting *Sancfi*, 875 F.3d at 646)).

25. Thus, “a person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses[.]” *Id.* (citing *Grokster*, 545 U.S. at 934–37).

4. Contributory Infringement

26. Under 35 U.S.C. § 271(c), an accused infringer is liable for contributory infringement if it “offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use for an infringement of such patent, and not a particular staple article or commodity of commerce suitable for substantial noninfringing use.”

27. A patentee can prove contributory infringement by showing “1) that there is direct infringement, 2) that the accused infringer has knowledge of the patent, 3) that the component has no substantial noninfringing uses, and 4) that the component is a material part of the invention.” *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1325 (Fed. Cir. 2010).

5. A Promise Not to Infringe is Insufficient

28. An ANDA applicant’s guarantee not to infringe is unavailing. *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013); *see also id.* at 1278 (“[w]hat

[the ANDA applicant] has asked the FDA to approve as a regulatory matter is the subject matter that determines whether infringement will occur.”). As such, a “pledg[e] to follow internal manufacturing guidelines” that “will keep it outside the scope of the claims or [where the applicant] has even filed a declaration in the court stating that it will stay outside the scope of the claims does not overcome the basic fact that it has asked the FDA to approve, and hopes to receive from the FDA, approval to market a product within the scope of the issue claims.” *Id.* at 1278; *see also Par Pharm., Inc. v. Hospira, Inc.*, 835 F. App’x 578, 586 (Fed. Cir. 2020) (“Even where internal documents suggest that a generic product will not meet a claim limitation in practice, representations about the ANDA’s scope control the infringement analysis.”).

29. “[A]ny so-called certification pledging not to infringe cannot override the conclusion that when a drug manufacturer seeks FDA approval to market a generic compound within the scope of a valid patent, it is an infringement as a matter of law. Simply saying ‘But I won’t do it’ is not enough to avoid infringement.” *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1280 (Fed. Cir. 2013).

30. The holding of *Sunovion* is not limited to “specific situations where the information disproving infringement is not included in the ANDA.” *Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.*, 1-20-cv-00365-MN, at 4 (D. Del. Feb. 8, 2022) (Noreika, J.); *see also id.* at 6 (holding an expert’s “non-infringement opinions are based on a legally erroneous premise” where said expert “focused on biobatch data even though the ANDA specification made clear that the product fell within the scope of Plaintiff’s patent”).

6. Presumption of Infringement

31. Under 35 U.S.C. § 295 “[i]n actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds: (1) that a substantial likelihood exists that the product was

made by the patented process, and (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine, the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.”

32. Establishing a substantial likelihood of infringement only requires that the patentee “present evidence that would support a reasonable conclusion that the imported product was made by the patented process.” *Dasso Int’l, Inc. v. MOSO N. Am., Inc.*, No. CV 17-1574-RGA, 2021 WL 4427168, at *2 (D. Del. Sept. 27, 2021) (citation omitted). Additionally, “§ 271(g) was enacted to ‘extend protection to the products’ resulting from practicing a patented process and to ‘prevent circumvention of a U.S. process patentee’s rights through manufacture abroad and subsequent importation into the United States of products made by the patented process.’” *Syngenta Crop Prot., LLC v. Willowood, LLC*, 944 F.3d 1344, 1362 (Fed. Cir. 2019) (citation omitted).

33. When determining whether a reasonable effort was made by the plaintiff, “courts examine the patentee’s discovery efforts and consider whether the patentee followed all of the avenues of discovery likely to uncover the defendant’s process, including written discovery requests, facility inspections, first-hand observation of the process, independent testing of process samples, the use of experts, and depositions of the defendant’s officials. *Dasso Int’l, Inc. v. MOSO N. Am., Inc.*, No. CV 17-1574-RGA, 2021 WL 4427168, at *5 (D. Del. Sept. 27, 2021) (citation omitted).

7. Safe Harbor and Stockpiling

34. Under 35 U.S.C. § 271(e)(1), “[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological

products.”

35. However, the § 271(e)(1) exemption is not absolute, and “does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained.” *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015).

36. The § 271(e)(1) exemption does not apply to all uses while FDA approval is pending. *Amgen Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 853 (Fed. Cir. 2009).

37. In determining whether the safe harbor applies, “[e]ach of the accused activities must be evaluated separately.” *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1338 (Fed. Cir. 2019) (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 200 (2005)).

38. The safe harbor does not apply to protect “non-FDA commercial manufacturing or yield optimization purposes.” *Wilson Wolf Mfg. Corp. v. Sarepta Therapeutics, Inc.*, No. CV 19-2316-RGA, 2020 WL 7771039, at *5 (D. Del. Dec. 30, 2020); *see also Biogen, Inc. v. Schering AG*, 954 F. Supp. 391, 397 (D. Mass. 1996) (finding the safe harbor does not apply where company “spent \$24 million to stockpile and prepare to market [drug] immediately upon the anticipated, imminent FDA approval in order to access promptly the lucrative market”); *Amgen, Inc. v. Hospira, Inc.*, 336 F. Supp. 3d 333, 344-45 (D. Del. 2018), *aff’d*, 944 F.3d 1327 (Fed. Cir. 2019).

B. Infringement of the '066 Patent

39. Liquidia has infringed claims of the '066 patent pursuant to 35 U.S.C. §271(e) by submitting, maintaining, and/or resubmitting its NDA.

40. Whether Plaintiff has proven by a preponderance of the evidence that Defendant will directly infringe, pursuant to 35 U.S.C. § 271(a), one or more of Asserted Claims of the '066 patent by importing into and using within the United States Yonsung Fine Chemicals Co., Ltd.’s (“Yonsung”) treprostinil product and/or making, offering to sell, or selling within the United States

Defendant's Proposed Product that incorporates Yonsung's treprostinil product.

41. Whether Plaintiff has proven by a preponderance of the evidence that Defendant will directly infringe Asserted Claim 8 of the '066 patent pursuant to 35 U.S.C. § 271(a) by importing into and using within the United States Yonsung Fine Chemicals Co., Ltd.'s "Yonsung's treprostinil product and/or making, offering to sell, or selling within the United States Defendant's Proposed Generic Product that incorporates Yonsung's treprostinil product.

42. Whether Plaintiff has proven by a preponderance of the evidence that Defendant would induce Yonsung to infringe Asserted Claims 1, 2, 3, 6, and 9 of the '066 patent pursuant to 35 U.S.C. § 271(b) by encouraging Yonsung to make Yonsung's treprostinil product.

43. Whether Plaintiff has proven by a preponderance of the evidence that Defendant would induce Yonsung to infringe Asserted Claim 8 of the '066 patent pursuant to 35 U.S.C. § 271(b) by encouraging Yonsung to make Yonsung's treprostinil product according to the patented method.

44. Whether Plaintiff has proven by a preponderance of the evidence that Defendant has an affirmative intent to induce direct infringement of one or more of the Asserted Claims of the '066 patent.

45. Whether Plaintiff has proven a preponderance of the evidence that Defendant would contribute to the infringement of Asserted Claims 1, 2, 3, 6, and 9 of the '066 patent pursuant to 35 U.S.C. § 271(c) by selling, offering to sell, importing, or using Yonsung's treprostinil product, knowing that it was especially made or adapted for use in the patented compositions.

46. Whether Plaintiff has proven by a preponderance of the evidence that Defendant would contribute to infringement of Asserted Claim 8 of the '066 patent pursuant to 35 U.S.C. § 271(c) by selling, offering to sell, importing, or using Yonsung's treprostinil product, knowing

III. EXCEPTIONAL CASE

53. Under 35 U.S.C. § 285 “[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party.”

54. A finding of exceptional circumstances under 35 U.S.C. § 285, warranting an award of reasonable attorney fees, includes litigation conduct that causes competitive harm to a prevailing party. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551-52 (Fed. Cir. 1989); *Nilssen v. Osram Sylvania, Inc.*, 528 F.3d 1352, 1357-59 (Fed. Cir. 2008). Such misconduct includes an alleged infringer’s attempt to conceal or misconstrue facts in support of the alleged infringer’s defense. *See Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004, 1026-27 (Fed. Cir. 2008) (attempting “to shield” or “distance” a party from the patents-at-issue and “bad-faith business conduct” justify an exceptional case award); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1552 n.1 (Fed. Cir. 1989) (“engag[ing] in various discovery . . . abuses”); *see also Nilssen v. Osram Sylvania, Inc.*, 528 F.3d 1352, 1359-59 (Fed. Cir. 2008) (requiring a “context-specific” analysis to assess whether the conduct amounts to litigation misconduct).

55. Whether this case is an exceptional case within the meaning of 35 U.S.C. § 285, such that Plaintiff is entitled to recover its attorneys’ fees and costs.

IV. CLAIM CONSTRUCTION

56. Claim construction is an issue of law that is reserved for the court to determine. *Markman v Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). Proper claim construction of a patent’s claims requires review of the patent’s intrinsic evidence and, when appropriate, extrinsic evidence. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005). The intrinsic evidence to be considered includes the claims, specification, and prosecution history. *Id.* at 1314-17. When intrinsic evidence is unable to provide a clear construction, courts may use extrinsic evidence to assist in the interpretation including relevant scientific principles, the meaning of

technical terms, the state of the art, dictionaries, treatises, and inventor and expert testimony. *See id.* at 1317-18. The intrinsic, and if necessary extrinsic, evidence is used to give the claims their ordinary and customary meaning that a POSA, at the time of the invention, would have interpreted the terms to mean. *Id.* at 1313-14.

57. Claim construction is to interpret the claims to cover both “what the inventors actually invented and intend to envelop with the claim.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Because patents are given a presumption of validity by 35 U.S.C. § 282, claim construction should act to preserve the claims’ validity, except in cases where an invalidating construction would be the “only claim construction that is consistent with the claim’s language and the written description.” *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed.Cir.1999); *see also Marine Polymer Techs., Inc. v. Hemcon, Inc.*, 672 F.3d 1350, 1368 (Fed. Cir. 2012).

58. A patent’s specification “is always highly relevant to a claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576 (Fed.Cir.1996). “The court must always read the claims in view of the full specification.” *SanDisk Corp. v. Memorex Prod., Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005). Further, any claim construction that excludes a preferred embodiment “is rarely, if ever, correct.” *Vitronics*, 90 F.3d at 1583; *see also, e.g. SanDisk*, 415 F.3d at 1285; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 865 (Fed.Cir.2004).

59. During the claim construction phase of this case, culminating in an April 30, 2021, joint claim construction brief, neither party proposed any claim constructions for the ’793 patent. More particularly, Liquidia did not seek to construe “therapeutically effective” in the narrow way described in Dr. Hill’s expert reports.

60. Liquidia's Issues Of Law assert that Dr. Waxman has proffered a construction for "pulmonary hypertension" that is "untimely and, moreover, improper in light of the specification and prosecution history." It is neither. Liquidia disclosed its "pulmonary hypertension" §112 defenses on September 28, 2021 and Dr. Waxman offered his responsive opinions in his rebuttal report on validity in November 2021.

V. VALIDITY

A. Legal Standards

1. Presumption of Validity

61. The Asserted Claims are presumed to be valid, and the burden of proving invalidity of each claim rests with Liquidia. 35 U.S.C. § 282. The presumption that an issued patent claim is valid requires that an invalidity defense or counterclaim be proven by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). Clear and convincing evidence is evidence that gives rise to an "abiding conviction that the truth of [the] factual contentions are 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984). The presumption of validity and corresponding burden of proof in overcoming that presumption applies to each patent claim independently. *See Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050 (Fed. Cir. 1988); *Carroll Touch, Inc. v. Electro Mechanical Sys., Inc.*, 15 F.3d 1573, 1581 (Fed. Cir. 1993).

2. Level of Skill in the Art

62. The level of ordinary skill in the art is that of a hypothetical person presumed to have known the relevant art at the time of the invention. Factors that may be considered are (1) "types of problems encountered in the art," (2) "prior art solutions to those problems," (3) rapidity with which innovations are made," (4) "sophistication of the technology," and (5) "educational level of active workers in the field. In a given case, every factor may not be present, and one or

more factors may predominate.” *In re GPAC*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

63. The level of skill in the art may also be demonstrated by post-filing date articles. References that do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at around the time the invention was made. *Thomas & Betts Corp. v. Litton Sys., Inc.*, 720 F.2d 1572, 1581 (Fed. Cir. 1983) (explaining that references “though not technically prior art, were, in effect, properly used as indicators of the level of the ordinary skill in the art to which the invention pertained”); *In re Farrenkopf*, 713 F.2d 714, 720 (Fed. Cir. 1983).

3. What Constitutes Prior Art

64. 35 U.S.C. § 102 (pre-AIA) provides that: “A person shall be entitled to a patent unless – (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States[.]” In order for an on-sale bar to occur the device sold must embody each and every limitation of the claimed invention. *See Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1383, 51 U.S.P.Q.2d 1055 (Fed. Cir. 1999) (“[t]he ‘invention’ which has been offered for sale must, of course, be something circumscribed by metes and bounds of the claim. Hence, the first determination in the section 102(b) analysis must be whether the subject of the baring activity met each of the limitations of the claim, and thus was an embodiment of the invention.”).

65. The party challenging the validity of a patent bears the burden “by clear and convincing evidence on all issues relating to the status of [a publication] as prior art.” *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996); *Plexxikon Inc. v. Novartis Pharms. Corp.*,

67. “[O]ne’s own work is not prior art under § 102(a)” when “[b]ased on the uncontradicted evidence of record” that the alleged prior art “was authored” by the inventor. *Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 605 F. Supp. 1362, 1370 (D. Del.

Mar. 4, 1984).

68. “[A] desire to have a product that has a particular characteristic, but does nothing to provide any teachings on how to achieve that goal” does not qualify as § 102(a) prior art. *Endo Pharms. Inc. v. Actavis Inc.*, C.A. No. 1:14-cv-1381, 2017 WL 3731001, at *6 n.4 (D. Del. Aug. 30, 2017).

4. Public Accessibility

69. “Patents are presumed to be valid under 35 U.S.C. § 282, and Defendant[] accordingly bear[s] the burden of proving by clear and convincing evidence that an asserted reference or system is prior art under Section 102.” *Sunoco Partners Marketing & Terminals L.P. v. Powder Springs Logistics, LLC*, Civ. Action No. 17-1390-LPS-CJB, 2020 WL 9438750, at *2 (D. Del. Feb. 20, 2020) (citing *Sandt Tech. Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001)).

70. The determination of whether a document is a “printed publication” that qualifies as prior art hinges on “public accessibility.” *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016) (quoting *In re Hall*, 781 F.2d 897, 898-99 (Fed. Cir. 1986)). Public accessibility is the “touchstone in determining whether a reference constitutes a printed publication,” and a reference is considered publicly accessible only if it was “disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence[] can locate it.” *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008) (internal citations omitted).

71. “In making the determination as to whether a reference is publicly accessible, the Federal Circuit has enunciated several factors that provide guidance to the court. These factors include: (1) distribution or dissemination; (2) records accessible to the public; (3) indexing and cataloging in a meaningful way; (4) duration of the display; (5) expertise of the intended audience;

72. For references stored in libraries, public accessibility requires that the reference be both available at the library and sufficiently indexed or catalogued by the priority date. *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016); *In re KlcLfenstein*, 380 F.3d 1345, 1349 (Fed. Cir. 2004). “The test for public accessibility is not ‘has the reference been indexed?’ [The Federal Circuit] ha[s] explained that where indexing is concerned, whether online or in tangible media, the ultimate question is whether the reference was available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.” *Acceleration Bay, LLC v. Activision Blizzard Ind.*, 908 F.3d 765, 774 (Fed. Cir. 2018) (internal quotation marks omitted) (concluding that reference was not prior art because it was “not indexed in a meaningful way”).

73. A patent claim is not anticipated if it was not disclosed in a prior reference. *See, generally* 35 U.S.C. § 102. For a claimed invention to be anticipated by a qualifying prior art reference, the reference “must describe...each and every claim limitation[.]” *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1344 (Fed. Cir. 2012). While the elements may be disclosed inherently or expressly, they must be “arranged or combined in the same way as in the claim.” *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (citation omitted). Put another way, prior art can only anticipate a claim if it discloses all elements “in the same form and order as in

the claim.” *In re Chudik*, 851 F.3d 1365, 1372 (Fed. Cir. 2017) (citation omitted).

74. Additionally, the anticipating reference must enable the all the subject matter that “falls within the scope of the claims at issue. *Galderma Labs., L.P. v Teva Pharmaceuticals USA, Inc.*, 799 Fed.Appx 838, 842-843 (Fed. Cir. 2020) (citing *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). The enablement requirement requires enablement without undue experimentation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). Prior art is not considered to be enabling for the purposes of anticipation if it does not enable a person of ordinary skill in the art to carry out the invention. *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, 468 F.3d 1366, 1381 (Fed. Cir. 2006). *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). However, limitations that are missing from a prior art reference cannot be filled in simply because a skilled artisan would be able to envision them. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 851 F.3d 1270, 1274-75 (Fed. Cir. 2017) (“*Kennametal* does not permit the Board to fill in missing limitations simply because a skilled artisan would immediately envision them”).

75. A prior art reference does not anticipate a patent claim if the reference “must be distorted from its obvious design.” *In re Chudik*, 851 F.3d 1365, 1372 (Fed. Cir. 2017) (citation omitted). Importantly, anticipation “is not proven by ‘multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.’” *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1069 (Fed. Cir. 2017). Proof of indexing in a “meaningful way,” together with evidence that the indexing occurred by the critical date, may be necessary before the burden shifts to the patentee to prove otherwise. *In re Lister*, 583 F.3d 1307, 1312 (Fed. Cir. 2009).

6. Obviousness Under Pre-AIA 35 U.S.C. § 103

76. “The determination of obviousness is a legal conclusion based on underlying facts.” *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1290–91 (Fed. Cir. 2013). A patent claim is invalid for obviousness if “the differences between the subject matter sought to be patented and the prior

78. The defendant has the burden of proof with respect to all of the *Graham* factors, including any alleged absence of objective indicia of nonobviousness. *Am. Hosp. Supply Corp. v. Travenol Labs., Inc.*, 745 F.2d 1, 8 (Fed. Cir. 1984).

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F.3d 1075, 1088 (Fed. Cir. 2008).

80. As the Federal Circuit has explained post-*KSR*, retracting the path of the inventor with hindsight, and discounting the number and complexity of the alternatives, is always inappropriate for an obviousness test based on the language of 35 U.S.C. § 103 that requires the analysis to examine “the subject matter as a whole” to ascertain if it “would have been obvious at the time the invention was made.” *Ortho-McNeil*, 520 F.3d at 1363–64. The Federal Circuit explained that “at the time of invention, the inventor’s insights, willingness to confront and overcome obstacles, and yes, even serendipity, cannot be discounted.” *Id.* Thus, for an obviousness analysis, a flexible Teaching-Suggestion-Motivation (“TSM”) test “remains the primary guarantor against a non-statutory hindsight analysis.” *Id.* Skepticism of experts and copying, “constitutes independent evidence of nonobviousness.” *Id.*

81. The patentability of an invention “shall not be negated by the manner in which the invention was made.” 35 U.S.C. § 103; *Honeywell Int’l Inc. v. Mexichem Amanco Holding S.A.*, 865 F.3d 1348, 1356 (Fed. Cir. 2017) (explaining that this provision “was enacted to ensure that routine experimentation does not necessarily preclude patentability”).

82. When a patent challenger contends that a patent is obvious in light of a combination or modification of prior art references, the challenger must point to clear and convincing evidence that shows that there existed a reason to make the change. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356–57 (Fed. Cir. 2007); *Yamanouchi Pharm. Co. v. Danbury Pharmacal, inc.*, 231 F.3d 1339, 1344–45 (Fed. Cir. 2000) (affirming that defendants “did not show sufficient motivation for one of ordinary skill in the art at the time of the invention to take any one of the following steps, let alone the entire complex combination”); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383 (Fed. Cir. 1986) (“Focusing on the

83. Addressing the alleged obviousness of drug-drug interaction patents at issue in *Vanda*, the District of Delaware held that motivation to solve a problem does not render the solution obvious. *Vanda Pharms., Inc. v. Roxane Labs., Inc.*, 203 F. Supp. 3d 412, 427 (D. Del. 2016) (“Even if Mutlib provided a basis for a POSA to focus a study on the implications for iloperidone metabolism of mutations in the genes for the CYP2D6, it would have been impossible to predict the results.”), *aff’d on other grounds*, *Vanda*, 887 F.3d 1117.

85. “[K]nowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references to reach the particular claimed method.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373–74 (Fed. Cir. 2008); *see also Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371, 1377 (Fed. Cir. 2004) (“Recognition of a need does not render obvious the achievement that meets that need Recognition of an unsolved problem does not render the solution obvious.”); *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1353–54 (Fed. Cir. 2013) (holding that because the prior art did not disclose the discovered problem, there was no motivation to combine prior art references to solve the problem”); *Novartis Pharm. Corp. v. Watson Labs., Inc.*, 611 F. App’x 988, 995 (Fed. Cir. 2015) (“Even an obvious solution, however, does not render an invention obvious if the problem solved was previously unknown.”);

86. An invention is not obvious over a proposed modification or combination of the prior art that is taught away from, i.e., when a person of ordinary skill in the art, upon examining the reference, would be discouraged from following the path set out in the reference, or would be led in a direct divergent from the path that was taken by the applicant.” *Unigene Labs., Inc. v. Apotex Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011); *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1308–09 (Fed. Cir. 2010) (explaining that criticisms of patent challenger’s proposed modification taught away from claimed invention.”).

88. “Once a prima facie case of obviousness has been established, the burden shifts to the applicant to come forward with evidence of secondary considerations of non-obviousness to overcome the prima facie case.” *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 344

(D. Del. 2010) (citing *In re Huang*, 100 F.3d 135, 139 (Fed.Cir.1996)).

89. Objective evidence is often the most probative and cogent evidence of nonobviousness in the record. *Ortho-McNeil*, 520 F.3d at 1365. It “is not just a cumulative or confirmatory part of the obviousness calculus, but constitutes independent evidence of nonobviousness.” *Id.* Objective evidence such as unexpected results, failure of others, long-felt but unmet need, commercial success, and industry praise must be considered before a conclusion on obviousness is reached. *Id.* (“[T]his evidence is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness.”); *Hybritech*, 802 F.2d at 1380 (“Objective evidence . . . is not merely ‘icing on the cake.’”); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012) (holding that the district court erred by determining that the patents were obvious before considering the objective evidence of nonobviousness).

90. Objective evidence of nonobviousness must be commensurate in scope with the claims, but “absolute identity” is not required. *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.2d 1291, 1308–09 (Fed. Cir. 2011).

91. Objective evidence relating to a single claimed embodiment should be considered even if the claim covers multiple embodiments. *See In re Glatt Air Techs., Inc.*, 630 F.3d 1026, 1030 (Fed. Cir. 2011); *see also Genetics Inst.*, 655 F.3d at 1309 (applying *Glatt* in the context of unexpected results).

92. A presumption of nexus exists when the product relied on to show the objective indicia of nonobviousness is coextensive with the claims. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (“[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product

is the invention disclosed and claimed in the patent.” (citations and internal quotation marks omitted)). It is not necessary that the patented invention be solely responsible for the objective indicia in order for this factor to be given weight. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1273 (Fed. Cir. 1991).

93. Evidence that the claimed invention produces results that are unexpected in view of the closest prior art supports a finding of nonobviousness. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1306–07 (Fed. Cir. 2015).

94. Unexpected results that inherently flow from the claimed invention are evidence of nonobviousness and need not be described or proven in the patent specification. *See Knoll Pharm. Co. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004) (holding that later-developed evidence of unexpected results is relevant to nonobviousness).

95. The patent challenger has the burden of proving that none of the properties were unexpected. *See Am. Hosp. Supply Corp. v. Travenol Labs., Inc.*, 745 F.2d 1, 8 (Fed. Cir. 1984) (“[Patent holder] is under no compulsion either to prove a new and surprising result Rather, the burden was on [challenger] to establish the lack of new and surprising results or the lack of criticality.”).

96. Commercial success can be “shown by significant sales in a relevant market.” *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563 (Fed.Cir.1997). If a patentee is able to show commercial success, and “the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the invention.” *Id.*

97. The patented invention is to be presumed to have a nexus between commercial success and the claimed features “if the marketed product embodies the claimed features, and is coextensive with them.” *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120,

1130 (Fed. Cir. 2000).

98. Evidence of a long-felt but unmet need for the claimed invention supports a finding of nonobviousness. *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009). Whether a long-felt need is unmet must be evaluated as to the patent filing's date and not as of the date the patented product first enters the market if the date of market entry is later than the filing date. *Id.*

99. Evidence of industry praise weighs in favor of non-obviousness. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.2d 1034, 1048 (Fed. Cir. 2016) (“Evidence that the industry praised a claimed invention or a product that embodies the patent claims weighs against an assertion that the same claimed invention would have been obvious.”); *WBIP*, 829 F.3d at 1335 (finding that awards received by the patentee is “strong evidence of industry recognition of the significance and value of the claimed invention” and “weighs in favor of nonobviousness”); *Janssen Pharmaceutica N.V. v. Mylan Pharms., Inc.*, 456 F. Supp. 2d 644, 672 (D.N.J. 2006) (finding that awards and appreciation bestowed on the invention and its inventors were “further evidence that the invention would not have been obvious”).

100. “Industry participants, especially competitors, are not likely to praise an obvious advance over the known art.” *Apple*, 839 F.3d at 1048; *Genzyme Corp. v. Dr. Reddy's Labs., Ltd.*, Nos. 13-1506-GMS, 13-1508-GMS, 2016 WL 2757689, at *15 (D. Del. May 11, 2016) (determining that awards bestowed on the claimed invention is recognition of “widespread praise in the US and Europe and this weighs in favor of nonobviousness”); *Ffizer Inc. v. Mylan Pharms. Inc.*, 71 F. Supp. 3d 458, 476 (D. Del. 2014) (finding that the claimed invention “was a breakthrough in the industry, widely praised by researchers and doctors”), *cf. id.*, 628 F. App'x 764 (Fed. Cir. 2016); *Research Found cf State Univ. cf N.Y. v. Mylan Pharms. Inc.*, 723 F. Supp. 2d

638, 653 (D. Del. 2010) (noting that *inter alia*, industry praise for the invention is “strong evidence of secondary indicia of non-obviousness”).

101. Copying the patented invention is also evidence of non-obviousness. 21 C.F.R. § 314.94(a)(8)(iv) (stating that a generic applicant’s proposed label does not have to be identical to that of the reference listed drug if the generic drug product and the reference listed drug are produced by different manufacturers); *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 438 F. Supp. 2d 479, 496 (D. Del. 2006) (“The success of Lexapro® and its benefits compared to other SSRIs is also supported by the efforts of generic drug manufacturers, including Defendants to copy the claimed invention.”), *cf.*, 501 F.3d 1263 (Fed. Cir. 2007); *Janssen*, 456 F. Supp. 2d at 671 (finding copying based on multiple ANDAs filed with the FDA to market generic versions of the patented drug).

102. Copying the claimed invention, rather than one in the public domain, is evidence that the claimed subject matter would not have been obvious. *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 991 (Fed. Cir. 1988).

103. General skepticism of those in the art is persuasive evidence of non-obviousness. *See Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1478–79 n.3 (Fed. Cir. 1984). If industry participants or skilled artisans are skeptical about whether or how a problem could be solved or the workability of the claimed solution, it favors non-obviousness. *WBIP*, 829 F.3d at 1335.

104. Expressions of disbelief or skepticism from the time of the invention by experts in the field, including the independent technical experts hired by each party during the litigation, “constitute strong evidence of nonobviousness.” *Env’t Designs, Ltd. v. Union Oil Co. cf. Cal.*, 713 F.2d 693, 697–98 (Fed. Cir. 1983) (citing *United States v. Adams*, 383 U.S. 39, 52 (1966)).

105. Skepticism need not be premised on an idea that the claimed invention would be

“impossible,” “unworkable,” or “technically infeasible” to be evidence of non-obviousness. *Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372, 1378 (Fed. Cir. 2019). Indeed, a range of opinions by third parties can be probative, including mere “worry” or “surprise.” *Id.* (citing *Circuit Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1337 (Fed. Cir. 2015)).

106. Proceeding against accepted wisdom is evidence of nonobviousness. *See Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 958 (Fed. Cir. 1997) (citing *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986)).

107. Failure of others, including abandonment of FDA registration applications, is also evidence of nonobviousness. *See Knoll*, 367 F.3d at 1385.

7. Written Description

108. The written description requirement is met if the specification and the existing knowledge in the art reasonably convey “to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010). For a patent claim to be held invalid for lack of written description, it must be proven by clear and convincing evidence that the patent fails to provide a POSA a basis “to recognize that the inventor invented what is claimed.” *Id.* at 1351. The test for reasonably conveying possession of an invention is a flexible one, “requir[ing] an objective inquiry into the four corners of the specification from the perspective of a [POSA].” *Id.*

109. A failure to “specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented.” *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002).

110. “Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date.” *Immunex Corp. v. Sandoz Inc.*, 964 F.3d

1049, 1063 (Fed. Cir. 2020). “The [written description] requirement is applied in the context of the state of knowledge at the time of the invention.” *Zoltek Corp. v. U.S.*, 815 F.3d 1302, 1308 (Fed. Cir. 2016). The specification therefore “need not include information that is already known and available to the experienced public.” *Id.* (quoting *Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985, 987 (Fed. Cir. 2005)).

111. A specification implicitly satisfies the written description requirement if a POSA would find it “reasonably clear what the invention is and that the patent specification conveys that meaning.” *All Dental Prodx.*, 309 F.3d at 779. That is, the “reasonably conveys” standard does not require the disclosure and claims to match exactly. *Ariad Pharm.*, 598 F.3d at 1352 (“[T]he [written] description requirement does not demand any particular form of disclosure or that the specification recite the claimed invention in haec verba”).

112. Nor will a claim be invalidated simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. *See Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575-76 (Fed. Cir. 1985) (holding that specification’s disclosure preferring a lower operating range, yet indicating no upper limit, combined with the industry knowledge at the time, was sufficient for a POSA to discern that higher ranges could be used).

113. A patent applicant need only convey, “with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

114. The word “comprising” in a patent claim “suggests that there may be additional, unclaimed elements,” but such additional elements are not required. *See Technical Consumer*

Prods., Inc. v. Lighting Sci. Grp. Corp., 955 F.3d 16, 2020 WL 1696642, at *4 (Fed. Cir. 2020) (citing *Crystal Semiconductor Corp. v. TriTech Microelecs. Int’l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001)).

115. Neither the written description nor enablement requirements of 35 U.S.C. § 112 require support for unclaimed elements. *See Lochner Techs., LLC v. Vizio, Inc.*, 567 F. App’x 931, 938-39 (Fed. Cir. 2014) (vacating summary judgment of invalidity for lack of written description and agreeing with patentee that “there is no precedent requiring a patentee to disclose or enable unclaimed elements”).

116. “[A] patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed.” *Martek Biosci. Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1371 (Fed. Cir. 2009). Further, “[a]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.” *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (quoting *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001)); *see also Lampi Corp. v. Am. Power Prods., Inc.*, 228 F.3d 1365, 1378 (Fed. Cir. 2000) (holding written description sufficient to support claims covering non-identical half-shells where patent drawings, the only cited written description support, only disclosed identical half-shells).

8. Enablement

117. A patent is enabled if a person of ordinary skill in the field could make and use the invention without having to perform undue experimentation. 35 U.S.C. § 112 ¶ 1; *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

118. Factors considered in determining whether experimentation is undue or excessive include: (1) the scope of the claimed invention; (2) the amount of guidance presented in the patent; (3) the amount of experimentation necessary; (4) the time and cost of any necessary

experimentation; (5) how routine any necessary experimentation is in the applicable field; (6) whether the patent discloses specific working examples of the claimed invention; (7) the nature and predictability of the field; and (8) the level of ordinary skill in the field. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

119. Even a considerable amount of routine experimentation required to practice a claimed invention does not violate the enablement requirement. *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013); *PPG Indus. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1565 (Fed. Cir. 1996).

120. “[T]he enablement requirement is met if the description enables any mode of making and using the invention.” *Invitrogen Corp. v. Clontech Labs. Inc.*, 429 F.3d 1052, 1070-71 (Fed. Cir. 2005) (quoting *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998)).

121. The specification preferably omits information that would already be known to a POSA. *Streck v. Res. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012).

122. Patent claims do not necessarily lack enablement because they embrace inoperative embodiments, assuming that a POSA in the related field would not be required to perform undue experimentation to determine which embodiments would work. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984). Further, “[i]t is not a function of the claims to specifically exclude . . . possible inoperative substances . . .” *Id.* at 1576 (quoting *In re Dinh-Nguyen*, 492 F.2d 856, 858–59, 181 USPQ 46, 48 (CCPA 1974)).

9. Definiteness

123. A determination of claim definiteness is a question of law. *Personalized Media Commc’ns, LLC v. Int’l Trade Comm’n*, 161 F.3d 696, 705 (Fed. Cir. 1998).

124. A party seeking to prove indefiniteness must do so by clear and convincing

evidence. *See Microsoft*, 564 U.S. at 95.

125. Indefiniteness of a claim is evaluated from the perspective of a person skilled in the relevant art. *See Nautilus, Inc.*, 134 S. Ct. at 2128. Moreover, the claim is evaluated in light of the patent's specification and prosecution history, and measured as of the time of the patent application. *Id.* Thus, reference to publications or patents in the specification are part of that disclosure, and are included in the inquiry of whether a claim, read in light of the specification and prosecution history, informs "with reasonable certainty" those skilled in the art about the scope of the invention, even if such references are not incorporated by reference. *Atmel Corp.*, 198 F.3d at 1383 (stating that "the district court erred by failing to consider the knowledge of one skilled in the art that indicated, based on unrefuted testimony, that the specification disclosed sufficient structure corresponding to the high-voltage means limitation" by citing, but not describing, a technical article); *see also Eli Lilly & Co. v. Teva Parenteral Medicines Inc.*, 845 F.3d 1357, 1370-72 (Fed. Cir. 2017) (holding the claim term "vitamin B12" as not indefinite when a person of ordinary skill in the art would understand the claim term in the context of the claim language, specification, and prosecution history).

126. A patent claim is not indefinite if "viewed in light of the specification and prosecution history," the claim "inform[s] those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus*, 572 U.S. at 910.

127. "The claims as granted are accompanied by a presumption of validity based on compliance with, inter alia, § 112 ¶ 2." *S3 Inc. v. Nvidia Corp.*, 259 F.3d 1364, 1367 (Fed. Cir. 2001).

128. The definiteness requirement is analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted

10. Collateral Estoppel

130. For purposes of collateral estoppel, “it is well settled that each claim of a patent is entitled to a presumption of validity and is to be treated as a complete and independent invention.” *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1137 (Fed. Cir. 1985) (citation omitted).

132. Relevant to the determination regarding whether collateral estoppel applies, process

133. To determine the validity of process claims, courts conduct a “fact-intensive comparison of the claimed process with the prior art.” *In re Ochiai*, 71 F.3d 1565, 1571 (Fed. Cir. 1995). Each process limitation must be taught by the prior art. *Id.*

135. Once the claims have been properly construed, to assess if collateral estoppel applies, the fact finder must determine

Westwood Chem., Inc. v. United States, 525 F.2d 1367, 1375 (Ct. Cl. 1975).

136. “Assignor estoppel applies when an invalidity defense in an infringement suit conflicts with an explicit or implicit representation made in assigning patent rights.” *Minerva*

Surgical, Inc. v. Hologic, Inc., 141 S. Ct. 2298, 2311 (2021).

137. “[A]ssignor estoppel is an equitable doctrine that prohibits an assignor of a patent or patent application, or one in privity with him, from attacking the validity of that patent when he is sued for infringement by the assignee.” *Semiconductor Energy Lab’y Co. v. Nagata*, 706 F.3d 1365, 1369 (Fed. Cir. 2013).

138. The doctrine of “[a]ssignor estoppel also prevents parties in privity with an estopped assignor from challenging the validity of the patent. Whether two parties are in privity depends on the nature of their relationship in light of the alleged infringement. The closer that relationship, the more the equities will favor applying the doctrine of assignor estoppel. Assessing a relationship for privity involves evaluation of all direct and indirect contacts.” *Mentor Graphics Corp. v. Quickturn Design Sys.*, 150 F.3d 1374, 1379 (Fed. Cir. 1998) (quoting *Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990)) (internal quotation marks and citations omitted).

139. A non-exhaustive list of factors for evaluating whether privity exists for assignor estoppel include: (1) the assignor’s leadership role at the new employer; (2) the assignor’s ownership stake in the defendant company; (3) whether the defendant company changed course from manufacturing non-infringing goods to infringing activity after the inventor was hired; (4) the assignor’s role in the infringing activities; (5) whether the inventor was hired to start the infringing operations; (6) whether the decision to manufacture the infringing product was made partly by the inventor; (7) whether the defendant company began manufacturing the accused product shortly after hiring the assignor; and (8) whether the inventor was in charge of the infringing operation. *Mag Aerospace Indus., Inc. v. B/E Aerospace, Inc.*, 816 F.3d 1374, 1380 (Fed. Cir. 2016) (citation omitted); see *Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d

789, 794 (Fed. Cir. 1990) (finding privity between an employer and an inventor hired as Vice President with responsibilities for developing the accused product); *Juniper Networks, Inc. v. Palo Alto Networks, Inc.*, 15 F. Supp. 3d 499, 508 (D. Del. Feb. 6, 2014) (finding privity between an employer and an employee granted the title of “founder”).

140. Further, privity exists between an assigning inventor and a party infringing a patent when “the ultimate infringer availed itself of the inventor’s ‘knowledge and assistance’ to conduct infringement.” *Intel Corp. v. U.S. Int’l Trade Comm’n*, 946 F.2d 821, 839 (Fed. Cir. 1991) (quoting *Shamrock Techs.*, 903 F.2d at 794). Indeed, even consultants or contractors will be found to be in privity with the infringer when that consultant or contractor plays a “significant role” in the infringing product. *Leading Tech. Composites v. MV2, LLC*, No. CCB-19-1256, 2020 WL 790601, at *4 (D. Md. Feb. 18, 2020); *BASF Corp. v. Aristo Inc.*, 872 F. Supp. 2d 758, 776 (N.D. Ind. May 29, 2012).

12. Product-by-Process

141. The general rule of product-by-process validity is to focus on the product, and not the process by which the product is made. *Amgen Inc. v. F. Hoffmann–La Roche Ltd.*, 580 F.3d 1340, 1369 (Fed.Cir.2009). However, there is an exception to this general rule, where the process imparts “structural and functional differences” into the product which distinguishes it from the prior art product. *Greenliant Sys.*, 692 F.3d at 1268–69 (citation omitted). This is especially true where “the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.” *Id.* at 1268 (citation omitted).

B. Validity of the '066 Patent

142. That Liquidia has failed to meet its burden of proving, by clear and convincing evidence, that any claim of the '066 patent is invalid pursuant to 35 U.S.C. §§ 102, 103, or 112.

C. Validity of the '901 Patent

143. That Liquidia is estopped, pursuant to 35 U.S.C. §315(e)(2), from asserting or maintaining any ground of invalidity that it raised or could have raised in the IPR relating to the '901 patent. *Novartis Pharms. Corp. v. Par Pharm. Inc.*, C.A. No. 15-0078-RGA, 2019 WL 9343055, at *2 (D. Del. Apr. 11, 2019); *see Brit. Telecomms. PLC v. IAC*, C.A. No. 18-366-WCB, 2019 WL 4740156, at *8 (D. Del. Sept. 27, 2019) (“any conclusion” will “limit[] the arguments”); *freal Foods, LLC v. Hamilton Beach Brands, Inc.*, C.A. No. 16-41-CFC, 2019 WL 1558486, at *1-2 (D. Del. Apr. 10, 2019) (the estoppel inquiry is broad, and merely “limited to whether the [] reference could reasonably have been discovered by a ‘skilled searcher conducting a diligent search’” (citing *Parallel Networks Licensing, LLC v. IBM Corp.*, C.A. No. 13-2072 (KAJ), 2017 WL 1045912, at *11 (D. Del. Feb. 22, 2017))); *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 330 F. Supp. 3d 574, 600 (D. Mass. 2018) (“the statute makes no distinction between successful and unsuccessful grounds”); *see also New Hampshire v. Maine*, 532 U.S. 742, 749-50 (2001) (recognizing judicial estoppel includes an inquiry into whether a prevailing party presents an “inconsistent position in a later proceeding”).

144. That Liquidia has failed to meet its burden of proving, by clear and convincing evidence, that any claim of the '901 patent is invalid pursuant to 35 U.S.C. §§ 102, 103, or 112.

D. Validity of the '793 Patent

145. That Liquidia is estopped, pursuant to the doctrine of assignor estoppel, from asserting or maintaining grounds of invalidity against the '793 patent.

146. That Liquidia is or will be estopped, pursuant to 35 U.S.C. §315(e)(2), from asserting or maintaining any ground of invalidity that it raised or could have raised in the pending IPR relating to the '793 patent. *Novartis Pharms. Corp. v. Par Pharm. Inc.*, C.A. No. 15-0078-

RGA, 2019 WL 9343055, at *2 (D. Del. Apr. 11, 2019); see *Brit. Telecomms. PLC v. IAC*, C.A. No. 18-366-WCB, 2019 WL 4740156, at *8 (D. Del. Sept. 27, 2019) (“any conclusion” will “limit[] the arguments”); *freal Foods, LLC v. Hamilton Beach Brands, Inc.*, C.A. No. 16-41-CFC, 2019 WL 1558486, at *1-2 (D. Del. Apr. 10, 2019) (the estoppel inquiry is broad, and merely “limited to whether the [] reference could reasonably have been discovered by a ‘skilled searcher conducting a diligent search’” (citing *Parallel Networks Licensing, LLC v. IBM Corp.*, C.A. No. 13-2072 (KAJ), 2017 WL 1045912, at *11 (D. Del. Feb. 22, 2017))); *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 330 F. Supp. 3d 574, 600 (D. Mass. 2018) (“the statute makes no distinction between successful and unsuccessful grounds”).

147. That Liquidia has failed to meet its burden of proving, by clear and convincing evidence, that any claim of the ’793 patent is invalid pursuant to 35 U.S.C. §§ 102, 103, or 112.

EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,)
)
Plaintiff,)
) C.A. No. 20-755-RGA
v.)
)
LIQUIDIA TECHNOLOGIES, INC.,)
)
Defendant.)

J. Caleb Boggs Courthouse
844 North King Street
Wilmington, Delaware

Friday, March 4, 2022
9:51 a.m.
Pretrial Conference

BEFORE: THE HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

APPEARANCES:

MORRIS NICHOLS ARSHT & TUNNELL LLP
BY: MICHAEL J. FLYNN, ESQUIRE

-and-

GOODWIN PROCTER LLP
BY: WILLIAM JACKSON, ESQUIRE
BY: HUIYA WU, ESQUIRE

-and-

McDERMOTT WILL & EMERY
BY: DOUGLAS H. CARSTEN, ESQUIRE
BY: ADAM BURROWBRIDGE, ESQUIRE
BY: ART P. DYKHUIS, ESQUIRE

For the Plaintiff

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APPEARANCES CONTINUED:

SHAW KELLER, LLP
BY: NATHAN R. HOESCHEN, ESQUIRE

-and-

COOLEY LLP
BY: SANYA SUKDUANG, ESQUIRE
BY: JONATHAN R. DAVIES, ESQUIRE
BY: DOUG CHEEK, ESQUIRE
BY: BRITTANY CAZAKOFF, ESQUIRE
BY: ROBERT J. MINN, ESQUIRE

For the Defendant

Also Present:

Mr. Rusty Schundler

*** PROCEEDINGS ***

DEPUTY CLERK: All rise. Court is now in session. The Honorable Richard G. Andrews presiding.

THE COURT: All right. Please be seated.

This is the pretrial conference in *United Therapeutics vs. Liquidia Technologies*, Civil Action Number 20-755.

And so, for the Plaintiff, Mr. Flynn, good morning.

MR. FLYNN: Good morning, Your Honor.

THE COURT: Who's sitting at the table with you?

MR. FLYNN: Sure. I have William Jackson and

09:51:47 1 Huiya Wu from Goodwin Procter. Adam Burrowbridge, Art
09:51:51 2 Dykhuis and Doug Carsen from McDermott Will & Emery.

09:51:56 3 THE COURT: Good morning. Way faster than I
09:51:58 4 could possibly absorb that.

09:52:01 5 Who do you have over on this side here?

09:52:04 6 MR. HOESCHEN: Good morning, again, Your Honor.
09:52:06 7 Nate Hoeschen from Shaw Keller on behalf of Defendant. With
09:52:08 8 me at counsel table, I have Sanya Sukduang, and Jonathan
09:52:11 9 Davies from Cooley, as well as Rusty Schundler from
09:52:15 10 Liquidia. And behind us here we have Brittany Cazakoff,
09:52:19 11 Doug Cheek and Robert Minn from Cooley.

09:52:21 12 THE COURT: Okay. All right. Well, good
09:52:24 13 morning to you all.

09:52:24 14 So, I read the Pretrial Order. I've read the
09:52:30 15 motions in limine. I'm prepared to rule on them. Prepared,
09:52:40 16 I think, to rule on basically the issues that were
09:52:44 17 highlighted in the Pretrial Order.

09:52:48 18 There was one thing that I had a question about
09:52:55 19 which was: So, there's a motion filed by the Plaintiff for
09:53:00 20 what I would call the 295 presumption. And even though
09:53:05 21 we're a few weeks away from trial, the parties stipulated to
09:53:15 22 delay that briefing, which I denied because it didn't make
09:53:24 23 much sense to me from what I could see.

09:53:26 24 But does somebody want to explain to me, is this
09:53:29 25 important to you all or why are we talking about delaying

09:53:32 1 the 295 briefing?

09:53:34 2 MR. DAVIES: Your Honor, I can address the
09:53:37 3 request for extension. The request for extension was made
09:53:40 4 because we thought it was untimely. The parties were trying
09:53:43 5 to complete a Pretrial Order.

09:53:45 6 That being said, Your Honor, our response will
09:53:47 7 be ready on Tuesday, and we'll be prepared to file opposing
09:53:50 8 responses on Tuesday.

09:53:51 9 THE COURT: Okay. Thank you.

09:53:59 10 All right. So, let's go through the Pretrial
09:54:01 11 Order. And when I say go through, I'm going through the
09:54:05 12 things that I marked as being disputes. If I miss a
09:54:09 13 dispute, you know, there will be -- let me know.

09:54:16 14 So, one was on Page 12, and it had to do with
09:54:27 15 using deposition designations of the parties' own officers
09:54:32 16 and employees. And the Plaintiff said, Well, let's go by
09:54:37 17 the rules here. And the Defendant said, No, let's change
09:54:42 18 the rules.

09:54:43 19 So, my question is: Why shouldn't I go with
09:54:48 20 Plaintiff since they're saying, Let's follow the rules?

09:54:53 21 MR. SUKDUANG: Your Honor, this is just simply a
09:54:54 22 matter of trial housekeeping. We have three days. I think
09:54:58 23 it pertains to really one witness from Liquidia.

09:55:02 24 THE COURT: Who is that?

09:55:05 25 MR. SUKDUANG: Mr. Kindig. And it really just

09:55:07 1 pertains to what evidence Plaintiff presents at trial with
09:55:13 2 respect to infringement. If it's really -- they took his
09:55:18 3 deposition. It's probably a few minutes of deposition
09:55:21 4 transcripts. If you need him live, then we'll bring him,
09:55:24 5 but really it's a matter of trying to be --

09:55:27 6 THE COURT: All right. Well, if you need him
09:55:29 7 live, you should bring him. So, I will go with the
09:55:32 8 Plaintiff's proposal.

09:55:32 9 All right. On Page 15 to 16, there's a dispute,
09:55:49 10 which as I could see it, is contingent upon the outcome of
09:55:54 11 the 295 briefing. So, what I thought, since I take it
09:55:59 12 you're in agreement that if the 295 motion is not granted, I
09:56:05 13 think your proposals are the same; right?

09:56:15 14 MR. JACKSON: William Jackson on behalf of
09:56:19 15 United Therapeutics. Yes, that's my understanding as well.

09:56:21 16 THE COURT: Okay. Let's put it in the Pretrial
09:56:27 17 Order what you both agree on, and you can put in a footnote
09:56:32 18 saying if the 295 motion is granted, then the Order will be
09:56:47 19 as Plaintiff proposes it in that alternative.

09:56:53 20 Okay?

09:56:54 21 MR. SUKDUANG: I have a question on that, if I
09:56:56 22 may, Your Honor. In Plaintiff's alternative if the 295 is
09:56:59 23 granted, they've requested presenting their case-in-chief on
09:57:04 24 infringement on '793. We present our opposition, but then
09:57:09 25 they get to rebut infringement on '793 and rebut

09:57:14 1 infringement on '066. Our understanding is, and we had
09:57:18 2 asked for rebuttal on invalidity and they said, no. So, it
09:57:22 3 doesn't seem to be appropriate if they present their
09:57:24 4 evidence on '793 that they don't get a rebuttal on '793.
09:57:28 5 And if the presumption has shifted, they've already admitted
09:57:32 6 that that's the best they can present. Why do they get a
09:57:35 7 rebuttal on the '066?

09:57:37 8 THE COURT: All right. Well, to the extent that
09:57:41 9 what you're saying is --

09:57:47 10 MR. SUKDUANG: It's bullet point four.

09:57:49 11 THE COURT: No, no. I'm sorry. I was just
09:57:51 12 checking to make sure, because what you have on the thing
09:57:55 13 you agree on is basically whoever has the burden of proof
09:57:59 14 goes first. The other side goes second and we're done.

09:58:02 15 MR. SUKDUANG: Right. First, correct, Your
09:58:04 16 Honor, they're changing that in their proposal.

09:58:07 17 THE COURT: Right. Well, that's the way it
09:58:09 18 should be if the 295 motion is granted.

09:58:14 19 MR. JACKSON: Agreed, Your Honor.

09:58:15 20 THE COURT: So, you may need to change it
09:58:17 21 because it does -- you know, I didn't pay a lot of attention
09:58:19 22 to it because it wasn't objected to on the basis that has
09:58:23 23 just been raised, but it does look like perhaps there was a
09:58:29 24 point there.

09:58:30 25 Okay?

09:58:30 1 MR. JACKSON: Yes, Your Honor.

09:58:31 2 THE COURT: All right. On Page 60 at the bottom
09:58:38 3 going over to the next page, there's a dispute about closing
09:58:42 4 argument. So, basically closing argument is not going to
09:58:48 5 count against the ten-and-a-half hours of trial time. And
09:58:54 6 if you want to have closing argument, we can have it on the
09:59:00 7 Thursday morning following the three days of trial. And I
09:59:06 8 think I had a time, but I lost track of what that is.

09:59:10 9 I think I have something else. In any event, if
09:59:16 10 I don't come up with it, let me ask: What do I have
09:59:19 11 scheduled on that Thursday morning?

09:59:21 12 (Discussion held off the record:)

09:59:28 13 THE COURT: Okay. Well, we can have closing
09:59:30 14 argument at 8:30 a.m. on the Thursday, and that will just
09:59:34 15 be -- it will be limited to some amount of time in the
09:59:40 16 neighborhood of 30 to 45 minutes per side, but we can
09:59:49 17 discuss that more later.

09:59:53 18 Oh, yeah. Okay. Right. 8:30 a.m. on Thursday.

09:59:58 19 So, then there's somewhere in here. Oh, yeah,
10:00:03 20 then we started to have the additional matters. So, as I
10:00:13 21 understand it, Liquidia wants to try the invalidity or
10:00:24 22 validity of the '901 patent.

10:00:28 23 Besides for retrying the case that you did in
10:00:31 24 front of the PTAB, do you have other invalidity and '901
10:00:37 25 patent cases that you want to try?

10:00:39 1 MR. SUKDUANG: Yes, Your Honor. We actually
10:00:41 2 made an offer to Defendant when we had our meet and confer
10:00:44 3 for the pretrial submission, and we had offered to
10:00:46 4 streamline the case, given that there's three days and
10:00:49 5 ten-and-a-half hours that we would forego any invalidity on
10:00:53 6 the '901 at trial here. If UTC appeals the Court's claim
10:01:00 7 construction that led to non-infringement to the Federal
10:01:03 8 Circuit and is remanded, we would bring those issues at that
10:01:06 9 time.

10:01:07 10 So, we're willing to get rid of the '901 now
10:01:09 11 reserving our right to bring our invalidity if there's a
10:01:12 12 remand. But to your question --

10:01:14 13 THE COURT: Well, wait. Hold on. Because I
10:01:16 14 understood that was not your position when the Pretrial
10:01:21 15 Order was written.

10:01:23 16 Is that what the Plaintiff wants to do?

10:01:27 17 MR. SUKDUANG: We're not sure. They haven't
10:01:28 18 responded to our offer.

10:01:29 19 THE COURT: Yes, now they're about to.

10:01:31 20 MR. JACKSON: So, Your Honor, the offer was
10:01:34 21 actually conditioned on some other things as well. In our
10:01:37 22 view, the '901, considering that, A, there's a stipulation
10:01:42 23 of --

10:01:43 24 THE COURT: Well, I understand.

10:01:44 25 MR. JACKSON: -- non-infringement, it should all

10:01:46 1 be pushed to --

10:01:47 2 THE COURT: Well, so let me tell you what I'm
10:01:49 3 going to do, which is this: You can keep talking about it
10:01:54 4 between yourselves, but as we get to the motions in limine,
10:02:00 5 I'm not going to let the Defendant do anything that they
10:02:10 6 could have done in front of the PTAB. That's, in my
10:02:16 7 opinion, statutorily estopped because of the final written
10:02:20 8 decision. My view is, and this actually includes the things
10:02:27 9 that you won on, it certainly includes things that you lost
10:02:30 10 on because or that you -- where you say, well, the claim
10:02:37 11 construction was wrong.

10:02:40 12 So, if they have other '901 defenses that they
10:02:44 13 want to do, I think we ought to get them done. But if
10:02:50 14 there's a dispute between you, but if -- but I'm also
10:02:55 15 agreeable if you want to stipulate or otherwise agree to
10:03:02 16 the -- that the rest of the '901 defenses are preserved for
10:03:09 17 in the event of a remand on the stipulated non-infringement.
10:03:14 18 I'm good with that, too. But the default is that we'll try
10:03:19 19 everything that the Defendant wants to try at the trial.

10:03:26 20 MR. SUKDUANG: Your Honor, and we do have some
10:03:28 21 112 defenses, but we'll speak to counsel and we're willing
10:03:31 22 to push those if there's --

10:03:32 23 THE COURT: Yeah, so speak -- you don't need
10:03:33 24 to -- you should speak to each other. Like I said, it's in
10:03:37 25 your ball park now. Okay?

10:03:40 1 MR. JACKSON: Yeah.

10:03:41 2 THE COURT: Okay. All right.

10:03:47 3 So, then there was a question about the
10:03:51 4 statutory estoppel on the '793 patent which is at Pages 19
10:04:00 5 and 20 of the Pretrial Order. And so, as I understand it,
10:04:05 6 there's no final written description at the PTAB. So, by
10:04:12 7 law, Defendant can present whatever it wants to in terms of
10:04:17 8 the '793 patent; right?

10:04:21 9 MR. SUKDUANG: Yes, Your Honor. If you're
10:04:22 10 following the '901, then the similar applies to '793.
10:04:25 11 There's no statutory estoppel.

10:04:27 12 THE COURT: Well, there's no final written
10:04:30 13 decision, so it's the same thing; right?

10:04:32 14 MR. SUKDUANG. Right. The estoppel is based on
10:04:33 15 the final decision. There's none in the '793, so we agree
10:04:36 16 with you. That's our position.

10:04:37 17 THE COURT: Sorry. I didn't get what you --
10:04:39 18 what about you?

10:04:39 19 MR. JACKSON: So, Your Honor, Axinn agreed
10:04:41 20 there's no final written decision, so estoppel would not
10:04:45 21 apply. To the degree if this would extend beyond August
10:04:49 22 11th, I believe the date is, I recall the Court in another
10:04:53 23 case had the circumstance where the PTAB issued a final
10:04:55 24 written decision after trial, but before the decision. And
10:04:58 25 we just wanted to identify that there's the possibility that

10:05:01 1 that might happen here, too.

10:05:02 2 THE COURT: No, I appreciate that and, you know,
10:05:08 3 I'm certainly not -- I have zero interest in racing the PTAB
10:05:13 4 to a decision here. And I don't -- you said the PTAB's
10:05:26 5 decision, that's due in mid-August?

10:05:29 6 MR. JACKSON: I believe it's August 11th, if I'm
10:05:31 7 not mistaken.

10:05:33 8 MR. SUKDUANG: That could get first pushed, Your
10:05:35 9 Honor, because Plaintiffs have continued to ask for
10:05:37 10 extensions in that even as of yesterday. So, it's still up
10:05:40 11 in the air, but yes, it should be some time in August some
10:05:43 12 time.

10:05:43 13 THE COURT: Well, put it like this, so, you can
10:05:45 14 put the case on or, I mean, you can put your case on.
10:05:53 15 There's no guarantee that I will actually decide it. But,
10:05:59 16 and to the extent you have, of course, non, you know, 112 or
10:06:05 17 defenses or something else, you can obviously put them on
10:06:08 18 because the PTAB won't decide because they're not barred and
10:06:12 19 PTAB won't rule on those. So, okay. So, in any event, the
10:06:24 20 Defendant can put that on.

10:06:27 21 All right. So, the 295 presumption, I will
10:06:32 22 decide that after we finish the briefing.

10:06:37 23 There is an argument in here about the plain and
10:06:43 24 ordinary meaning of pulmonary hypertension. And I read what
10:06:46 25 the parties submitted because it's in the Pretrial Order.

10:06:50 1 Other than reading it, I didn't do anything else. It
10:06:54 2 certainly struck me, just based on reading it, that the
10:07:00 3 opinion of the Plaintiff's expert, pulmonary hypertension is
10:07:06 4 pulmonary arterial hypertension struck me as a losing
10:07:12 5 position. But, you know, I don't usually decide these
10:07:18 6 things just based on, I don't know, kind of offhand remarks
10:07:23 7 in a Pretrial Order.

10:07:24 8 So, the question is: What do you want to do
10:07:29 9 about this? You know, we can do some expedited claim
10:07:35 10 construction before trial. We can have people testify at
10:07:39 11 trial. There's probably other things that creative lawyers
10:07:44 12 can think of that we can do.

10:07:45 13 And have you all talked to each other about
10:07:48 14 this?

10:07:49 15 MR. SUKDUANG: No, but we've thought about it,
10:07:50 16 Your Honor.

10:07:50 17 THE COURT: Okay. Well, that's a start.

10:07:53 18 MR. SUKDUANG: Yeah. Well, again, we're trying
10:07:54 19 to expedite. We're trying to not put additional papers
10:07:57 20 because you've got the 295 now. If the testimony wants to
10:08:00 21 go in at trial, we're fine with that, but the witness,
10:08:06 22 Dr. Waxman, should not now submit a new report on his
10:08:11 23 intrinsic evidence or extrinsic evidence relying --
10:08:14 24 supporting his construction because his report simply says
10:08:17 25 in one paragraph, the '793 patent, which is the question

10:08:21 1 that the patent pertains to, covers multiple cases. And
10:08:25 2 then later on he says, oh, maybe it's just pulmonary
10:08:28 3 arterial hypertension.

10:08:29 4 So, I think you can just go and weigh his
10:08:32 5 credibility and look at the issue from that perspective.
10:08:36 6 But we don't believe additional -- now, that UT has raised
10:08:40 7 it at this point, and given the time to trial, we don't
10:08:47 8 think additional briefing should be allowed on claim
10:08:51 9 construction. If they believe it's the plain and ordinary
10:08:53 10 meaning, then he should have been able to cite that in his
10:08:55 11 expert report.

10:08:57 12 THE COURT: All right.

10:08:58 13 MR. JACKSON: So, as you can imagine, I disagree
10:09:01 14 with much of what Mr. Sukduang has described, but I agree
10:09:06 15 that we will put on a witness and be able to provide his
10:09:10 16 testimony. And the Court will be able to weigh his
10:09:13 17 testimony and his credibility to be able to determine what
10:09:16 18 the term actually means and how it's used in the patent,
10:09:20 19 according to a person of ordinary skill.

10:09:22 20 And so, we're happy, if the Court wants
10:09:24 21 briefing, we're happy to do it, but I don't think it's
10:09:27 22 necessary.

10:09:27 23 THE COURT: Okay. Well, I hear both sides
10:09:30 24 saying they don't want to do briefing unless they have to.
10:09:38 25 You know, I guess the only thing, and so I'm inclined to

10:09:43 1 just push off the trial with essentially the agreement of
10:09:51 2 the parties if that's what I should do. One of the things
10:10:02 3 that occurs to me is, based on what the Defendant said in
10:10:10 4 their papers, a significant part of their argument is what I
10:10:22 5 would call pure claim construction. It's based on the
10:10:27 6 intrinsic record.

10:10:28 7 My impression is that what Plaintiff's expert
10:10:32 8 says is not based on intrinsic record. And so, I guess, the
10:10:46 9 way I hear you all talking, it's not as though there's some
10:10:51 10 defense expert who's going to be testifying about this and
10:10:59 11 Plaintiff's expert is going to say or may say, pulmonary
10:11:02 12 hypertension means pulmonary arterial hypertension and a
10:11:06 13 person of ordinary skill in the art could understand that.
10:11:08 14 But then blah, blah, blah, whatever the rest of their
10:11:10 15 opinions are that were based on that.

10:11:13 16 And what I hear Mr. Sukduang saying is they're
10:11:20 17 happy to just cross-examine the expert about this. And I
10:11:23 18 suppose, do I understand the situation correctly?

10:11:31 19 MR. SUKDUANG: Our expert, Dr. Hill, who's the
10:11:33 20 corollary to Dr. Waxman in his report and what we intend to
10:11:37 21 present at trial is a brief recitation of what a POSA looks
10:11:41 22 at in the '793, including the examples, which were
10:11:44 23 illustrative. And in the very first paragraph of the first
10:11:48 24 column -- so, he doesn't have testimony that's directly on
10:11:54 25 point to the issue because it just came up during the

10:11:57 1 deposition.

10:11:58 2 But the evidence we will present will be
10:12:02 3 intrinsic evidence. We'll make very clear that the term
10:12:06 4 pulmonary hypertension refers to five groups of diseases and
10:12:12 5 their claim is to the umbrella. They're trying to restrict
10:12:15 6 it to just one to preserve validity.

10:12:18 7 THE COURT: Right, right. I saw that much or I
10:12:19 8 saw that general argument in the papers. Okay. Yes, sir.

10:12:24 9 MR. JACKSON: Just to the degree, what you're
10:12:26 10 asking is we expect to put on a witness, and they expect to
10:12:29 11 cross-examine, and that's the way the Court will hear the
10:12:32 12 evidence. I think that's what I heard their question is.
10:12:35 13 And I think the answer to that question is yes.

10:12:37 14 MR. SUKDUANG: And sure, it's just as long as
10:12:39 15 we've -- and I did say -- Mr. Jackson didn't mention this.
10:12:44 16 He's confined with his expert report just like every expert
10:12:47 17 is. And so, the absence of any extrinsic evidence, we'll
10:12:52 18 reserve our right at that particular time to object.

10:12:57 19 THE COURT: Okay. All right.

10:13:00 20 Well, in any event, so the question of whether
10:13:03 21 pulmonary hypertension means pulmonary hypertension or it
10:13:09 22 means pulmonary arterial hypertension is something that will
10:13:14 23 be addressed at trial by the agreement of the parties and
10:13:18 24 presumably be resolved by me at some later point.

10:13:22 25 All right. So, there's something in the

10:13:26 1 Pretrial Order about a Mr. Bunce, B-U-N-C-E and Dr. Byrd.
10:13:33 2 And as I read it, the Plaintiff followed the rules. And at
10:13:43 3 this point, Liquidia says, Well, we'd like to depose them.
10:13:49 4 We'd like to have a proffer. They may be duplicative, blah,
10:13:53 5 blah, blah.

10:13:55 6 I'm kind of of the general view that if the
10:13:59 7 Plaintiff followed the rules, it's too late for any of the
10:14:03 8 things that the Defendant wants to be doing.

10:14:05 9 MR. SUKDUANG: Could I just on one point?
10:14:08 10 Plaintiff had 20 individuals on their initial disclosures.
10:14:13 11 We were restricted in hours of depositions. We served
10:14:16 12 30(b)(6) notices on the very subject matter, the topics nine
10:14:21 13 and topic 22, on the very subject matter. Mr. Bunce and
10:14:25 14 Dr. Byrd were identified in the initial disclosures.

10:14:29 15 UTC identified corporate designees for those
10:14:32 16 topics who are not on their initial disclosures at all.

10:14:36 17 THE COURT: Which they can do; right?

10:14:38 18 MR. SUKDUANG: Which they can do, but we have
10:14:40 19 corporate testimony on these very issues which UTC said
10:14:44 20 these are the individuals, their corporate witnesses, that
10:14:47 21 have the best information regarding it. If they're
10:14:50 22 presenting in the course of discovery that other individuals
10:14:54 23 are more knowledgeable or have better subject matter on
10:14:57 24 these particular topics, then going to look at Mr. Bunce and
10:15:01 25 Dr. Byrd to depose them on the exact same issues seemed

10:15:06 1 duplicative at that particular time.

10:15:07 2 At the very least, if they're going to be
10:15:09 3 allowed to testify, there should be some proffer as to what
10:15:13 4 they're going to do because we're not trying to try this by
10:15:16 5 surprise. And this is a surprise because they represented
10:15:20 6 to us, Here is our corporate testimony on the subject matter
10:15:24 7 these two witnesses are going to be testifying about. We
10:15:28 8 don't like the corporate testimony we did from the other
10:15:31 9 individuals. We're going to bring these guys.

10:15:33 10 So, it is a trial by surprise. We followed --
10:15:35 11 they did follow the rules. We followed the rules. They
10:15:39 12 chose other individuals to present the testimony on this
10:15:42 13 exact subject matter that these witnesses apparently have
10:15:47 14 relevant information on.

10:15:49 15 So, we ask that in a normal circumstance if we
10:15:52 16 didn't ask 30(b)6 topics on this, yeah, we screwed up. But
10:15:57 17 we specifically sought the subject matter of what these two
10:15:59 18 witnesses would testify about through corporate testimony,
10:16:03 19 and they chose other individuals. We think it's a different
10:16:06 20 circumstance.

10:16:07 21 THE COURT: All right. Mr. Jackson.

10:16:10 22 MR. JACKSON: So, I actually believe that the
10:16:12 23 topics that are identified in the 30(b)(6) don't exactly
10:16:16 24 line up with the topics that we identified in the initial
10:16:20 25 disclosures for these witnesses. These witnesses were

10:16:23 1 identified in the initial disclosures with those various
10:16:26 2 topics, and there was plenty of time left within -- the
10:16:30 3 Court in the initial pretrial or initial Scheduling Order
10:16:34 4 had a hundred hours' worth of deposition testimony for each
10:16:37 5 side. There was plenty of time left to depose these two
10:16:42 6 individuals within those hundred hours. They didn't do it.

10:16:45 7 We identified these as witnesses with knowledge.
10:16:48 8 We intend to be able to use them as appropriate and
10:16:52 9 necessary for our case.

10:16:53 10 THE COURT: And I take it that if they say, on
10:16:57 11 whatever points the Rule 30(b)(6) depositions covered, if
10:17:01 12 they say something different, the Defendant will be able to
10:17:08 13 put forth the Rule 30(b)(6) witness saying something
10:17:11 14 different?

10:17:12 15 MR. JACKSON: Absolutely, Your Honor. That's
10:17:13 16 when a 30(b)(6) -- it's the whole purpose of a 30(b)(6)
10:17:18 17 witness.

10:17:18 18 THE COURT: So, Mr. Sukduang, in the papers UTC
10:17:29 19 said what Mr. Jackson just said, which is you had time left
10:17:33 20 over in the deposition hours. I take it this is true?

10:17:40 21 MR. SUKDUANG: We did have time, but we also had
10:17:43 22 the testimony that they were supposed to cover. And so,
10:17:49 23 we're at a point where they have a corporate witness saying
10:17:52 24 this is what the corporate position is. Why would -- if
10:17:56 25 they presented Mr. Poisson, who is one of the 30(b)(6)

10:18:00 1 witnesses not on their initial disclosures, but who they
10:18:03 2 designated, if they presented Mr. Poisson for trial, okay.
10:18:06 3 He's on that topic that Dr. Byrd and Mr. Bunce were on.

10:18:09 4 If they present Dr. Batra at trial who was the
10:18:13 5 corporate designee with respect to the research and
10:18:16 6 development of TYVASO, which is what these witnesses talk
10:18:19 7 about, great. He's live at trial.

10:18:21 8 But whether we have time left over or not, it's
10:18:25 9 not a matter of the time left over. It's a matter of they
10:18:29 10 presented the corporate testimony, what the position of the
10:18:32 11 company is through other individuals, and now they're trying
10:18:36 12 -- these witnesses, all they have to -- if you look at what
10:18:38 13 the initial disclosure is, it's the NDA and the research
10:18:42 14 development of TYVASO.

10:18:44 15 So, those were the topics. So, if they have
10:18:46 16 testimony of the corporate position, it's not going to be
10:18:49 17 their own personal opinion that these individuals are
10:18:52 18 testifying about. They're going to be testifying about what
10:18:53 19 UTC's position is.

10:18:55 20 We already have that testimony. They already
10:18:58 21 presented that testimony through Mr. Poisson and Dr. Batra,
10:19:01 22 so bring those individuals to trial --

10:19:03 23 THE COURT: All right.

10:19:11 24 MR. SUKDUANG: -- or offer a proffer and take a
10:19:14 25 short deposition of them, so we at least have an idea of

10:19:17 1 what they're going to say and how we're going to impeach
10:19:19 2 them given the prior testimony.

10:19:30 3 THE COURT: All right. Well, I think to the
10:19:36 4 extent that these people, Mr. Bunce and Dr. Byrd, are called
10:19:45 5 to testify and they say things that are the same as what the
10:19:48 6 corporate witnesses said, okay. And to the extent they say
10:19:53 7 something different, you know, that's part of the reason why
10:19:57 8 you have the corporate witness is so you can introduce their
10:20:05 9 positions through that testimony.

10:20:07 10 So, I'm not going to exclude Mr. Bunce and
10:20:12 11 Dr. Byrd, and I'm not going to make Plaintiff do a proffer,
10:20:17 12 and I'm not going to order that they be put up for
10:20:20 13 deposition.

10:20:22 14 All right.

10:20:23 15 MR. SUKDUANG: Your Honor, on that question, can
10:20:24 16 we use the Poisson and two 30(b)(6) corporate testimony,
10:20:27 17 because it's not of those individuals. It's of the UTC
10:20:30 18 corporation.

10:20:31 19 Can we use that as impeachment for Mr. Bunce and
10:20:36 20 Dr. Byrd? Because, again, that testimony is of the
10:20:38 21 corporation. Our understanding is those individuals were in
10:20:41 22 the corporation.

10:20:42 23 THE COURT: So, the point is you can use it.
10:20:44 24 Whether you can use it to impeach somebody else, you know,
10:20:48 25 probably not, but you can use it to show that somebody else

10:20:53 1 is wrong.

10:20:55 2 I mean, if they're saying -- you know, as a
10:21:01 3 general matter in ANDA cases, what non-expert witnesses say
10:21:09 4 counts for zero. So, I think we're arguing over something
10:21:13 5 of not much importance here. But to the extent they say
10:21:17 6 something that's important, presumably you have somebody
10:21:21 7 else from UTC saying whatever they say.

10:21:26 8 And if it's significant to you, you can present
10:21:30 9 that. And you can certainly, you know, cross-examine having
10:21:35 10 knowledge of what the people otherwise say, but I don't
10:21:43 11 think something that a corporate witness said can -- you
10:21:49 12 know, it's not a prior inconsistent statement of Dr. Bunce
10:21:52 13 and Dr. Byrd, so for that point you can't just say, isn't it
10:21:55 14 true you said this before because they didn't say it.

10:21:58 15 MR. SUKDUANG: But it's prior inconsistent
10:22:00 16 statements of UTC which is --

10:22:01 17 THE COURT: Yeah, so that's the reason why you
10:22:03 18 can use it to say that -- I don't think there's a rule that
10:22:09 19 says, oh, because a designee said something, you can use it
10:22:12 20 to impeach an individual.

10:22:14 21 MR. SUKDUANG: But he's not testifying as an
10:22:16 22 individual, he's testifying as a corporate witness.

10:22:17 23 THE COURT: Well, no. They've got to be
10:22:19 24 testifying as an individual. If they testify as a corporate
10:22:22 25 witness, then you can object on the basis of hearsay and

10:22:25 1 all. You know, there is no corporate witness of trial
10:22:28 2 testimony.

10:22:28 3 MR. SUKDUANG: And that's the confusion as to
10:22:30 4 what these individuals are going to testify about. That's
10:22:32 5 why the proffer -- but we understand. We'll play -- our
10:22:35 6 understanding is if we -- if you think there's testimony
10:22:37 7 from the corporate witness that we think is important, we
10:22:40 8 can just play it in the normal course of our designations?

10:22:43 9 THE COURT: Sure. Right. I mean, that's
10:22:45 10 exactly why you took the 30(b)(6) in the first place or, I
10:22:49 11 mean, that's one of the reasons.

10:22:50 12 MR. SUKDUANG: And they're not testifying as
10:22:52 13 corporate witnesses then is our understanding.

10:22:53 14 THE COURT: Well, they can't, right,
10:22:54 15 Mr. Jackson?

10:22:55 16 MR. JACKSON: I agree. That's what Rule 32
10:22:58 17 provides. It specifically provides that you can play a
10:22:59 18 30(b)(6) witness as a -- in --

10:23:01 19 THE COURT: Right. So, Mr. Bunce and Dr. Byrd,
10:23:05 20 whatever testimony they give at trial, it should be based on
10:23:07 21 personal knowledge.

10:23:10 22 Okay. All right.

10:23:14 23 There's some stuff in the Pretrial Order about
10:23:16 24 the collateral estoppel res judicata, whatever it is,
10:23:22 25 motions pending in front of Judge Hall. And so, and I think

10:23:28 1 you have an argument on that on Tuesday of next week.

10:23:31 2 MR. SUKDUANG: It's Thursday the 10th, I

10:23:33 3 believe, at 2:30 p.m.

10:23:35 4 THE COURT: Okay. Thursday the 10th.

10:23:37 5 MR. SUKDUANG: Is that --

10:23:38 6 MR. JACKSON: That's what I have as well.

10:23:39 7 THE COURT: I'm sorry. I don't know. Oh, you

10:23:39 8 know --

10:23:45 9 MR. SUKDUANG: Tuesday is our 295.

10:23:47 10 THE COURT: Yeah, yeah. I confused it. My
10:23:48 11 notes here, I confused it with that because I had seen when
10:23:53 12 I was trying -- when I was denying the motion to continue
10:23:56 13 it, and I saw you were saying, Well, let's file it on March
10:24:00 14 11th, that's when I saw that Judge Hall had the argument on
10:24:04 15 March 10th.

10:24:05 16 So, it seems to me likely, because this is the
10:24:09 17 way Judge Hall usually does stuff, she will probably rule on
10:24:13 18 your motion on March 10th, though that's not a guarantee and
10:24:18 19 I'm not her representative. So, obviously, she can do
10:24:21 20 anything she wants, but she frequently rules from the bench.

10:24:27 21 Is there anything about that motion for summary
10:24:32 22 judgment in terms of whatever her ruling is that you want to
10:24:35 23 talk about right now?

10:24:36 24 MR. SUKDUANG: Yes, Your Honor. So, our
10:24:38 25 understanding is if Judge Hall -- when Judge Hall issues her

10:24:43 1 decision, whenever that might be, it's a Report and
10:24:46 2 Recommendation.

10:24:46 3 THE COURT: Yeah.

10:24:47 4 MR. SUKDUANG: If she grants the motion, then
10:24:51 5 the '066 and '901 patents technically go away, but you need
10:24:59 6 to adopt the Report and Recommendation.

10:25:01 7 THE COURT: Yeah, no. Yeah, yeah.

10:25:03 8 MR. SUKDUANG: So, it's the timing of that with
10:25:04 9 respect to trial and then whether, depending on the outcome,
10:25:10 10 I'm sure if we prevail, UTC will submit a paper saying don't
10:25:15 11 adopt it. There was some errors. If she doesn't adopt our
10:25:20 12 position, we may file a paper.

10:25:22 13 So, how do you want to deal with that in terms
10:25:25 14 of the timing of trial?

10:25:26 15 THE COURT: Well, it seems to me my question is:
10:25:28 16 How do you want to deal with it? Because my default is
10:25:30 17 there is a schedule you have that the loser has -- well,
10:25:34 18 actually if anybody wants to object has 14 days, and it's
10:25:39 19 14 days to reply.

10:25:40 20 I think that's the schedule, right, Mr. Flynn?

10:25:42 21 MR. FLYNN: Yes, Your Honor.

10:25:43 22 THE COURT: Yeah. So, all things being equal, I
10:25:53 23 might not rule on the objections until after the trial is
10:25:56 24 over. In fact, under that schedule, I'm pretty sure I don't
10:26:02 25 even have all of the objections until the trial is over.

10:26:05 1 So, you know, depending on what she says, maybe that makes
10:26:10 2 sense, maybe it doesn't make sense. I don't know.

10:26:13 3 I guess I'm asking you all: Is there anything
10:26:18 4 in particular --

10:26:25 5 MR. SUKDUANG: Well, we believe, Your Honor --

10:26:26 6 THE COURT: Do you want to do this outside of
10:26:28 7 the normal course of events?

10:26:29 8 MR. SUKDUANG: Yes. If we were to prevail on
10:26:32 9 summary judgment, the '066 and '901, which are the 30(b)
10:26:38 10 30-month stay blocking patents, not the '793, there would be
10:26:44 11 a Report and Recommendation that they are invalid. At that
10:26:47 12 point we believe that those two patents should not be tried
10:26:51 13 during the bench trial.

10:26:55 14 And to the extent UTC wants to lodge objections,
10:26:59 15 that should be expedited because it doesn't make sense when
10:27:05 16 you have a Report and Recommendation on summary judgment to
10:27:08 17 get rid of patents to just litigate those patents again.
10:27:13 18 That's the point of summary judgment. And so, we believe
10:27:20 19 that if she grants the motion, those patents should come off
10:27:27 20 subject to any objection and your recommendation adopting
10:27:32 21 it.

10:27:32 22 THE COURT: All right. So, let me just go over
10:27:35 23 a couple of things you said. One of which is: Is it true
10:27:38 24 that the 30-month stay has nothing to do with the '793
10:27:43 25 patent?

10:27:43 1 MR. JACKSON: That's correct, Your Honor.

10:27:45 2 THE COURT: Okay.

10:27:46 3 MR. JACKSON: The '793 -- the Complaint was
10:27:48 4 filed --

10:27:49 5 THE COURT: You don't need to explain to me why.
10:27:52 6 I believe you. And so, basically I already know that for
10:27:59 7 the '901 patent, there's no basis for -- I may not be saying
10:28:14 8 this exactly right, but since the '901 patent is stipulated
10:28:17 9 to be non-infringed, that's not much of a basis for
10:28:22 10 preventing the Defendant from launching. I'm not saying
10:28:27 11 people can't argue it, but it's, obviously, a bad position.

10:28:31 12 So, the other patent, which I guess is the --

10:28:35 13 MR. SUKDUANG: The '066 patent.

10:28:36 14 THE COURT: '606?

10:28:37 15 MR. SUKDUANG: '066.

10:28:39 16 THE COURT: '066. So, from a practical
10:28:42 17 perspective, that's kind of the key patent in this case at
10:28:45 18 this point?

10:28:45 19 MR. SUKDUANG: That's really the primary issue
10:28:48 20 that's preventing Liquidia's new drug application from being
10:28:52 21 approved. We have tentative approval. That's the block
10:28:55 22 from final approval.

10:28:56 23 THE COURT: Okay. All right.

10:29:01 24 Mr. Jackson, do you have any comment here?

10:29:03 25 MR. JACKSON: Yes. So, coming back to where

10:29:05 1 Your Honor started this question, so assuming Judge Hall
10:29:10 2 issues her Report and Recommendation on March 10th, 14 days
10:29:14 3 later would be March 24th. Whoever's objections would be
10:29:17 4 due then, 14 days after that would be April 7th, which is
10:29:21 5 when the responses of those objections would be due. We
10:29:25 6 think whoever is going to lose is likely to issue
10:29:28 7 objections.

10:29:29 8 THE COURT: Oh, yeah. I'd bet money on that.

10:29:32 9 MR. JACKSON: Right. And so, and the response
10:29:35 10 of those objections are not due until after trial. We think
10:29:38 11 it makes more sense to either way try both the '066 and '793
10:29:43 12 because either way if we're going to have a trial, we should
10:29:49 13 have both patents in it. It's much more efficient than,
10:29:53 14 say, if she were to rule and then the Court were to reverse
10:29:56 15 her, then we'd have to have a trial some time in the summer
10:30:00 16 for just the '066 because it wouldn't have been covered in
10:30:03 17 the trial and then would have been resuscitated as it were.

10:30:07 18 THE COURT: All right. And remind me of one
10:30:09 19 thing, and I don't think either counsel has said so far, the
10:30:14 20 30-month stay that goes with the '066 patent, when does that
10:30:18 21 one end?

10:30:19 22 MR. JACKSON: I have that as October 24th.

10:30:22 23 MR. SUKDUANG: Yes.

10:30:22 24 THE COURT: Okay. Thank you.

10:30:25 25 MR. SUKDUANG: Part of the reason why, Your

10:30:26 1 Honor, that this summary judgment was pushed is we filed it.
10:30:31 2 Now, you know, there was a certain time period within the
10:30:34 3 Scheduling Order. We did that. UTC asked for an extension
10:30:36 4 of time to file their opposition because we're in the middle
10:30:39 5 of experts. Then they filed their 295, you know, where they
10:30:44 6 do it.

10:30:44 7 So, part of the issue here is they've pushed
10:30:50 8 this out to reach this conclusion. We, of course, agreed to
10:30:57 9 the extension because we wanted to be good Court assistance.

10:31:04 10 THE COURT: No, and I appreciate that. I guess
10:31:06 11 the thing is that the trial in this is scheduled for
10:31:25 12 March --

10:31:26 13 MR. SUKDUANG: 28th.

10:31:27 14 MR. JACKSON: 28th, Your Honor.

10:31:28 15 THE COURT: -- 28th. Okay. Well, the thing of
10:31:35 16 it is this, no matter what Judge Hall decides, and no matter
10:31:39 17 really how quickly you all file objections, it's not
10:31:49 18 particularly reasonable to expect that I will decide this
10:31:53 19 before the scheduled trial date. And so, I think the best
10:31:59 20 course is to just plan to try the '066 and the '793 patent
10:32:11 21 and whatever it is you decide about invalidity on the '901
10:32:16 22 patent.

10:32:17 23 And, you know, you're already ready to go on it.
10:32:26 24 And, you know, I will decide the 295 motion after I get all
10:32:32 25 of the briefing on that some time before the trial.

10:32:39 1 So, basically, I think what we ought to do is
10:32:46 2 plan to have the full trial. If the decision of Judge Hall
10:32:53 3 on March 10th, you know, is such that something happens
10:33:14 4 so, you know, when she's ruled, there will be a concrete
10:33:21 5 basis to figure out what the most likely thing is. But
10:33:33 6 until she's ruled, it seems to me there's no reason to do
10:33:38 7 anything other than plan to go full steam ahead.

10:33:41 8 And if you need to talk to me on March 11th
10:33:50 9 based on what she's done, you know, call my chambers, and we
10:33:54 10 can have a conversation. But it strikes me that the most
10:34:00 11 efficient thing at this point is to just plan to have a
10:34:04 12 trial.

10:34:04 13 Okay. So, I also have a note here, a couple
10:34:16 14 notes, one of which is that say the Thursday before trial,
10:34:23 15 if each of you, each side can send me a binder with a
10:34:28 16 picture of your experts, to the extent you have them, a
10:34:32 17 picture of each of your expert witnesses, and no more than
10:34:36 18 two pages of their resume, that would be helpful to me. So,
10:34:47 19 I'd like to do that.

10:34:49 20 After we have the trial or while we're having
10:34:50 21 the trial, you need to provide a glossary of terms of names
10:34:55 22 to the court reporters the morning of trial. When playing
10:35:00 23 depositions, provide the court reporters with the
10:35:01 24 designations highlighted before the playing of the videos.
10:35:06 25 Provide the court reporter, in addition to both my law clerk

10:35:10 1 one for me and one for my deputy clerk with a copy of each
10:35:14 2 exhibit notebook at the same time as it is provided to the
10:35:17 3 witness.

10:35:18 4 And this part is very important, any corrections
10:35:23 5 to the trial transcript must be submitted to the court
10:35:26 6 reporter no later than two weeks after the last day of
10:35:30 7 trial. So, that would be the Wednesday two weeks after the
10:35:33 8 trial.

10:35:40 9 All right?

10:35:41 10 MR. SUKDUANG: Your Honor, can I ask one
10:35:42 11 question?

10:35:42 12 THE COURT: Sure.

10:35:43 13 MR. SUKDUANG: With respect to binders, there's
10:35:45 14 four copies. One to the court reporter and three --

10:35:48 15 THE COURT: Yes.

10:35:49 16 MR. SUKDUANG: Okay. I just wanted to make
10:35:50 17 sure.

10:35:50 18 THE COURT: Yeah, yeah, yeah. No problem.

10:35:52 19 In terms of briefing on the case, we'll decide
10:35:59 20 that probably at the same time as or during when we're doing
10:36:06 21 closing arguments, but I would appreciate it if you all
10:36:10 22 would consult with each other before then and try to work
10:36:16 23 out the joint proposal. No guarantee that I will adopt it,
10:36:20 24 but it would certainly help me to know what it is you think
10:36:23 25 is reasonable and not to be doing it on the fly on the

10:36:30 1 Thursday morning.

10:36:32 2 All right. So, we have in the pretrial how long
10:36:38 3 this is. Is there anything about -- in terms of the
10:36:44 4 witnesses, are you all squared away on that? All the
10:36:54 5 witnesses you need, they're available when you need them and
10:36:58 6 that sort of thing?

10:36:59 7 MR. SUKDUANG: From our perspective, and I think
10:37:01 8 the parties are trying to reach or have reached agreement,
10:37:05 9 unless something happens in COVID between now and trial,
10:37:09 10 that everybody is going to be live, not by Zoom. But, of
10:37:12 11 course, if COVID happens and they need to testify, I think
10:37:16 12 both sides should be able to work that out.

10:37:19 13 THE COURT: Okay. That's good.

10:37:20 14 MR. JACKSON: Let me also add I think the
10:37:22 15 parties have also said to the degree somebody is unavailable
10:37:25 16 when they would otherwise be called, we might call them out
10:37:28 17 of order in order to accommodate their schedule. And to the
10:37:31 18 degree -- I heard in the previous pretrial conference that
10:37:34 19 you held this morning the possibility of Zoom. I don't
10:37:37 20 expect that to happen, but to the degree it -- Mr. Sukduang
10:37:42 21 or we want to raise like, let's see if we can work that kind
10:37:45 22 of thing out, we'll try to work that out and present it to
10:37:48 23 Your Honor, if that's okay.

10:37:48 24 THE COURT: Okay. Yeah, that's good.

10:37:50 25 MR. JACKSON: Thank you.

10:37:53 1 THE COURT: So, unless there's something else
10:37:55 2 that you all want to talk about, the only other thing that I
10:38:03 3 have a note on is the motions in limine. But before I get
10:38:07 4 to them, is there anything else you all want to talk about?

10:38:10 5 MR. SUKDUANG: There was one issue from
10:38:13 6 Defendants, and again, it goes to the case narrowing that I
10:38:16 7 had mentioned earlier regarding the '901. You know, part of
10:38:21 8 most cases with the bench, you agree certain claims rise or
10:38:26 9 fall with like an independent claim or something like that.
10:38:29 10 We have ten-and-a-half hours. They have 11 experts on their
10:38:32 11 side, plus Mr. Bunce, Dr. Byrd, whoever else. So, that's
10:38:35 12 12, 13 witnesses they intend to call.

10:38:37 13 THE COURT: Yeah, I can't believe they're
10:38:39 14 serious about that.

10:38:40 15 MR. SUKDUANG: We proposed some sort of
10:38:43 16 agreement that, okay, claim 2 and 3 of some patent where
10:38:49 17 there really is no validity or infringement issue that
10:38:54 18 someone's saying, oh, we don't have purple dye crayon. And
10:39:00 19 that's not a validity position that they're relying on. Oh,
10:39:03 20 purple die crayons are the novel thing. Let's just say,
10:39:07 21 Hey, if claim 1 survives, claim 2 survives. If claim 2
10:39:10 22 falls, claim 2 falls. And that way that will also truncate
10:39:14 23 time. That's the proposal that we proposed in conjunction
10:39:17 24 with our '901 proposal as a streamlining issue for the case.

10:39:20 25 I don't think you need to hear testimony

10:39:22 1 regarding air dry vacuuming as part of one of the dependent
10:39:28 2 claims.

10:39:28 3 THE COURT: Okay. So, is this a proposal that
10:39:33 4 you presented very recently?

10:39:36 5 MR. SUKDUANG: We presented it when we were
10:39:37 6 doing the pretrial meet and confer under the Scheduling
10:39:41 7 Order where all these issues are to be discussed, which I
10:39:43 8 think was last -- not Wednesday of this week, but the
10:39:48 9 Wednesday prior.

10:39:49 10 THE COURT: Okay. All right.

10:39:50 11 Mr. Jackson.

10:39:51 12 MR. JACKSON: Just a short version is the
10:39:53 13 parties are discussing these issues trying to narrow issues
10:39:56 14 for trial, so we just have a limited set so we present the
10:40:00 15 most cogent case to Your Honor. We're working on that. We
10:40:02 16 said we'd get back to them shortly. In fact, there might
10:40:05 17 even be a stipulation of what's contested and what's not
10:40:08 18 contested. So, we can narrow that, but I think the parties
10:40:11 19 are continuing to try to work that out.

10:40:12 20 THE COURT: Okay. Well, I think that's
10:40:14 21 reasonable. You know, I've seen some cases recently where,
10:40:24 22 you know, somebody has an independent claim and three
10:40:26 23 dependent claims that go with it, and the argument is
10:40:32 24 entirely about the independent claim. You know, the
10:40:35 25 dependent claims add nothing, either both in terms of

10:40:40 1 infringement and invalidity. And I think this might have
10:40:44 2 been in front of a jury, and I'm wondering why are we doing
10:40:47 3 this.

10:40:47 4 So, in any event, I don't know what your case
10:40:52 5 is, so I'm not commenting on your case. But certainly, to
10:40:55 6 the extent that you can streamline it so that the disputed,
10:41:03 7 necessarily disputed issues are the ones you concentrate on,
10:41:07 8 you know, rise in my estimation, if that means anything.

10:41:11 9 Okay. So, the motions -- or is there anything,
10:41:16 10 Mr. Jackson, you want to bring up other than the motions in
10:41:19 11 limine?

10:41:20 12 MR. JACKSON: No, Your Honor, unless Your Honor
10:41:21 13 has any questions. No, thank you.

10:41:22 14 THE COURT: No, I think not. So, as I said, I
10:41:25 15 have read the motions in limine, and I've done some thinking
10:41:29 16 about these. And so, the Plaintiff's motion in limine
10:41:37 17 number one, Docket Item 323, the parties agree that the '393
10:41:45 18 patent is not prior art; right?

10:41:49 19 MR. SUKDUANG: Correct. We are not relying on
10:41:51 20 the '393 as prior art.

10:41:52 21 THE COURT: All you've got to do is say correct.
10:41:54 22 Thank you.

10:41:55 23 And then, the conclusion I draw is since it's
10:42:03 24 not prior art, for purposes of deciding obviousness, it's
10:42:06 25 irrelevant.

10:42:08 1 MR. SUKDUANG: Agreed. We're not presenting
10:42:11 2 that.

10:42:11 3 THE COURT: Okay. So, one of the things that
10:42:15 4 you do seem to want to present, Mr. Sukduang, is whether the
10:42:20 5 same product, which is TYVASO, is an embodiment of the
10:42:25 6 claims of the '393, the '901 and the '066 patents.

10:42:33 7 So, am I right that you want to present that?

10:42:36 8 MR. SUKDUANG: Yes, it's not TYVASO. It's the
10:42:38 9 active ingredient within the product, the trepostinil. It's
10:42:42 10 the API. So, it's not the whole approved drug, it's the API
10:42:46 11 within the drug.

10:42:49 12 THE COURT: So, why? What is that relevant to?

10:42:50 13 MR. SUKDUANG: That goes to our summary judgment
10:42:51 14 issue. So, to the extent --

10:42:53 15 THE COURT: Well, so the summary judgment issue
10:42:56 16 is you're either going to win it or lose it, but we're not
10:43:00 17 going to try it.

10:43:01 18 MR. SUKDUANG: Well, that depends on how the
10:43:04 19 timing of this all works. Because if Judge Hall says there
10:43:11 20 are factual issues that she cannot decide, and thus, denies
10:43:18 21 our summary judgment, then our expert addresses those
10:43:22 22 factual issues.

10:43:24 23 THE COURT: Okay.

10:43:25 24 MR. SUKDUANG: Claim estoppel is a legal issue,
10:43:28 25 we agree. They're saying there are lots of factual issues

10:43:30 1 you can't apply to that. So, that's how it pertains to
10:43:33 2 that.

10:43:33 3 THE COURT: Mr. Jackson, do you have something
10:43:35 4 to say or somebody on your side about that?

10:43:37 5 MR. JACKSON: Do you mind if my colleague,
10:43:39 6 Mr. Burrowbridge, addresses that?

10:43:40 7 THE COURT: Yeah, okay. I saw him kind of --

10:43:42 8 MR. JACKSON: Starting to get up.

10:43:44 9 THE COURT: Yes, Mr. Burrowbridge.

10:43:45 10 MR. BURROWBRIDGE: Thank you, Your Honor. So,
10:43:48 11 what Liquidia is attempting to do is just take the claims
10:43:51 12 out of the question of validity. And, in our view, that's
10:43:55 13 completely improper.

10:43:56 14 THE COURT: Wait, wait, wait.

10:43:57 15 MR. BURROWBRIDGE: The claims define --

10:43:58 16 THE COURT: Wait, wait. You said what Liquidia
10:44:03 17 is trying to do is take the claims out of the question of
10:44:08 18 invalidity?

10:44:09 19 MR. BURROWBRIDGE: Correct, Your Honor.

10:44:10 20 THE COURT: Now, I don't understand that
10:44:12 21 sentence.

10:44:13 22 MR. BURROWBRIDGE: Okay. So, Mr. Sukduang has
10:44:17 23 just explained that they are not asserting that the '393,
10:44:20 24 the patent itself is prior art --

10:44:21 25 THE COURT: Yes.

10:44:22 1 MR. BURROWBRIDGE: -- but they do want to
10:44:23 2 present the idea that the product of the '393 patent is the
10:44:28 3 same. They're essentially treating --

10:44:31 4 THE COURT: But they're saying it has nothing to
10:44:32 5 do with obviousness; right? They're saying that they want
10:44:38 6 to present it in connection with collateral estoppel; right?

10:44:43 7 I mean, and what I just understood Mr. Sukduang
10:44:49 8 to say is that's the sole reason they want to present this
10:44:53 9 testimony; right?

10:44:55 10 MR. BURROWBRIDGE: That is what I understand.

10:44:57 11 MR. SUKDUANG: Yes, for the '393, because it's
10:44:59 12 product-by-process claims. That's the important part. So,
10:45:01 13 the issue is the product, not the process. So, we're not
10:45:04 14 taking out the claim. The claim is the product.

10:45:06 15 THE COURT: But the reason you want to do it is
10:45:09 16 for your summary judgment argument, not for obviousness,
10:45:17 17 infringement, or, you know, some other --

10:45:23 18 MR. SUKDUANG: Correct.

10:45:24 19 THE COURT: -- issue. Your sole purpose in
10:45:28 20 wanting to do this has to do with proving disputed facts
10:45:32 21 relating to collateral estoppel --

10:45:35 22 MR. SUKDUANG: Correct.

10:45:35 23 THE COURT: -- or disputed facts, if Judge Hall
10:45:38 24 says they're disputed?

10:45:39 25 MR. SUKDUANG: Correct.

10:45:40 1 THE COURT: Okay. Yes, Mr. Burrowbridge.

10:45:41 2 MR. BURROWBRIDGE: The problem with that
10:45:42 3 approach, Your Honor, is that the claims in the product are
10:45:45 4 inseparable. The claims of the '393 patent describe and
10:45:51 5 limit the product of the '393 patent. The claims of the
10:45:54 6 '066 patent limit and describe the product of the '066
10:46:00 7 patent.

10:46:01 8 THE COURT: Right. So, what I think you're
10:46:03 9 saying goes, and it really goes to the merits of the
10:46:11 10 collateral estoppel argument in the first place; right? I
10:46:14 11 mean, isn't that -- I haven't read the collateral estoppel
10:46:17 12 briefs, so I'm, you know -- but I guess there was something
10:46:23 13 in the Pretrial Order about it. But isn't that the argument
10:46:27 14 you're making in front of Judge Hall that essentially the
10:46:33 15 claims are different, so who cares about the product?

10:46:35 16 MR. BURROWBRIDGE: It's similar, yes, Your
10:46:38 17 Honor. It's similar. And under that standard, the proper
10:46:41 18 standard, the correct standard for collateral estoppel is
10:46:45 19 whether or not the claims and, in this case, the product are
10:46:49 20 substantially identical. It's not whether the claims or
10:46:52 21 products are substantially identical, but whether the issue
10:46:54 22 of invalidity is substantially identical. So, in order
10:46:59 23 to --

10:47:00 24 THE COURT: Okay.

10:47:01 25 MR. BURROWBRIDGE: -- to determine --

10:47:01 1 THE COURT: So, Mr. Burrowbridge, sorry to cut
10:47:04 2 you off here. So, I'm not going to try disputed issues
10:47:10 3 related to collateral estoppel at this trial. I want to try
10:47:16 4 obviousness, infringement, any other invalidity defenses
10:47:21 5 that the Defendant has, which I thought I saw some.

10:47:26 6 And so, my opinion is that the testimony that
10:47:39 7 the product that's produced by the process of the three
10:47:48 8 patents is the same is irrelevant to the trial issues. And
10:47:58 9 so, I'm going to grant the Plaintiff's motions to the extent
10:48:04 10 what the motion is seeking to exclude, the argument that the
10:48:14 11 same product is a relevant fact, because the Defendant has
10:48:20 12 made it clear the only way that they would consider it a
10:48:23 13 relevant fact is in support of their collateral estoppel
10:48:26 14 argument.

10:48:29 15 Okay?

10:48:30 16 MR. BURROWBRIDGE: Yes, Your Honor. And we plan
10:48:32 17 to object if they intend to put forward argument or evidence
10:48:36 18 treating the '393 patent as prior art for purposes of the
10:48:40 19 process.

10:48:40 20 THE COURT: Yeah, yeah. So, Mr. Burrowbridge, I
10:48:43 21 don't know what the relationship between the parties is
10:48:48 22 here. I should say the counsel, but I think they made it
10:48:52 23 crystal clear that they're not saying that. So, saying you
10:48:55 24 reserve the right to preserve an objection if they're liars
10:48:59 25 isn't really helpful.

10:49:02 1 MR. BURROWBRIDGE: Thank you, Your Honor.

10:49:03 2 THE COURT: Okay. So, that same motion also
10:49:12 3 dealt with the question of what the effect of, I believe
10:49:23 4 it's 315(b) (2), what statutory estoppel is. And I read a
10:49:34 5 good number of the cases cited by the parties. The cases
10:49:44 6 cited by the Plaintiff, which included one of my cases said
10:49:56 7 various things, but one thing they didn't say was that
10:49:59 8 there's no inception for "successful grounds before the
10:50:10 9 PTAB." So, I was disappointed because I thought that, in
10:50:13 10 fact, that was the right argument.

10:50:17 11 And I did note a statement, and I don't have it
10:50:21 12 in front of me right now, I did note a statement in the
10:50:25 13 Federal Circuit's case in, I believe it was called *Caltech*
10:50:30 14 *vs. Broadcom* on February 4th of this year, Page 20 of the
10:50:36 15 slip opinion, where the Court made a very broad statement.
10:50:41 16 But, again, it was in a different context.

10:50:45 17 And, you know, in thinking about it, why is it
10:50:48 18 that, for the most part, the issue hasn't come up? It's
10:50:57 19 because, and this is something I actually said in the case
10:51:00 20 of mine that was cited which I think was called -- yeah, I
10:51:07 21 don't remember what it's called, but it was cited in a
10:51:12 22 string cite of Plaintiff's cases is the whole point of the
10:51:16 23 statutory estoppel was to shrink the amount of work that's
10:51:21 24 involved.

10:51:23 25 And when the Defendant chooses to litigate

10:51:28 1 issues in front of the PTAB, the statutory estoppel is
10:51:32 2 supposed to stop them from litigating those issues or ones
10:51:35 3 they could have raised at -- you know, the other
10:51:41 4 requirements, final written decision are made in front of a
10:51:45 5 judge.

10:51:46 6 And so, I looked because the Defendant cited
10:51:53 7 some cases, and they cited one of Judge Stark's, and they
10:51:56 8 cited one from, I think, New Jersey. And I looked at those
10:52:01 9 two cases, and what I think those cases were was a situation
10:52:10 10 where, I'm not sure about the case from New Jersey, but I
10:52:15 11 think Judge Stark, it was a jury trial. And so, you were
10:52:18 12 going to have a situation where Plaintiff wanted to try the
10:52:23 13 infringement case, and the Defendant said, I think, well,
10:52:29 14 somehow it's unfair that the Plaintiff gets to try an
10:52:34 15 infringement case, and the jury doesn't hear that the
10:52:37 16 patent's invalid.

10:52:41 17 And so, you know, one option in that situation
10:52:45 18 would be for the judge to postpone the trial and, you know,
10:52:49 19 wait until the invalid patent was finally determined to be
10:52:53 20 invalid and just then knock the whole -- you know, never try
10:52:57 21 it. But, on the other hand, sometimes that's not a very
10:53:05 22 efficient way to proceed.

10:53:07 23 So, what I took from looking at the cases, and
10:53:11 24 this is against the backdrop that I think what the statute
10:53:17 25 says is that, you know, a petitioner cannot pursue a

10:53:24 1 counterclaim based on "any ground that it raised or
10:53:29 2 reasonably could have raised during the instituted IPR that
10:53:34 3 has resulted in a final written decision."

10:53:37 4 I'll note that the part of that is me
10:53:40 5 rearranging the words of the statute. That's not how it
10:53:43 6 literally reads.

10:53:45 7 That's pretty broad and there are all kinds of
10:53:48 8 cases that say it's pretty broad. There is no exception for
10:53:52 9 successful grounds. If there were a jury, and there were
10:53:57 10 infringement claims, and the Defendant says that it was
10:54:02 11 unfair to exclude its successful grounds, that would be an
10:54:08 12 interesting issue, but that's not the issue that I have in
10:54:10 13 front of me.

10:54:11 14 My issue is or the issue now is just should I
10:54:14 15 permit the Defendant to repeat its successful case, which by
10:54:19 16 the way wouldn't include the two that it lost. And I think
10:54:25 17 the statutory estoppel applies. And so, I'm going to grant
10:54:30 18 Plaintiff's motion on that issue, too.

10:54:32 19 All right. So, we also --

10:54:35 20 MR. SUKDUANG: Your Honor, just one point on
10:54:37 21 that, and I think you ruled on that earlier.

10:54:38 22 THE COURT: Well, I did in passing because --

10:54:40 23 MR. SUKDUANG: Yes.

10:54:41 24 THE COURT: -- it was convenient, but --

10:54:42 25 MR. SUKDUANG: That's fine. Just the BTG case,

10:54:45 1 the New Jersey case, that was a Hatch-Waxman case, so it was
10:54:46 2 a non-jury trial. So, I just wanted to put that on the
10:54:48 3 record, but we understand your point.

10:54:49 4 THE COURT: Okay. I don't know why the judge --
10:54:51 5 you know, in the end maybe I just don't agree with that.
10:54:55 6 You know, Judge Stark's opinion, I understand why he did
10:54:57 7 what he did, but I think it was a pretty different
10:55:00 8 situation.

10:55:02 9 So, Plaintiff's motion in limine number two,
10:55:09 10 which has to do with the Ghofrani, G-H-O-F-R-A-N-I and
10:55:17 11 Voswinckel, V-O-S-W-I-N-C-K-E-L papers. And, again, I
10:55:29 12 looked at some case law, and so I understand the issue is
10:55:39 13 whether Ghofrani and Voswinckel are works "by others". And
10:55:53 14 then this has to do with the '793 patent.

10:55:57 15 And so, I looked at the list of inventors on the
10:56:02 16 '793 patent, which there are maybe seven of them. And two
10:56:11 17 people, I think one's Voswinckel, and the other one might be
10:56:15 18 Seeger, S-E-E-G-E-R, they are among the co-authors of the
10:56:26 19 two papers that the parties refer to as Ghofrani and
10:56:31 20 Voswinckel. But Ghofrani and Voswinckel, I think each have
10:56:34 21 five authors. And two or three of them are different than
10:56:43 22 the -- are not inventors in the patent.

10:56:53 23 So, on its face, you have different inventive
10:56:58 24 entities for the two pieces of prior art than you do for the
10:57:05 25 patent. And it seems to me, since the inventors on a patent

10:57:12 1 are presumed to be correctly named, that if nothing else
10:57:20 2 happens, then the Defendant is going to be a winner on the
10:57:27 3 issue that these two works are prior art. But I take it,
10:57:34 4 though I'm not sure exactly what it's going to be, that one
10:57:38 5 of the things some of these inventors are scheduled to
10:57:41 6 testify, I saw while I was skimming through the papers, that
10:57:46 7 there were lots of declarations submitted to the PTAB or the
10:57:52 8 Patent Trademark Office, but there are various things in the
10:57:54 9 record of the prosecution or somewhere there are
10:57:59 10 declarations from other people saying they did or didn't
10:58:02 11 invent this.

10:58:03 12 So, all of this is to say, I think this is a
10:58:07 13 trial issue, and I'll decide it after I hear what
10:58:14 14 everybody's admissible evidence is on this subject. So,
10:58:19 15 whether Ghofrani or Voswinckel are, in fact, prior art, it
10:58:24 16 is, therefore, an issue for trial to be decided after
10:58:27 17 consideration of the relevant admissible evidence.

10:58:30 18 Understood?

10:58:33 19 MR. SUKDUANG: Understood, Your Honor.

10:58:35 20 MR. BURROWBRIDGE: Understood, Your Honor.

10:58:36 21 THE COURT: Okay. And then we have the third
10:58:38 22 motion in limine, Docket Item 320, which is the Defendant's
10:58:43 23 motion in limine to exclude portions of Dr. Mahdi Fawzi's
10:58:48 24 rebuttal expert report. And so --

10:58:56 25 MR. SUKDUANG: Your Honor, on that point, so I

10:58:57 1 think that motion in limine, at least part of it, is tied to
10:59:01 2 the '393 issue that you decided earlier where we don't
10:59:06 3 present the '393 product issue. So, Dr. Fawzi, some of the
10:59:13 4 paragraphs we object to is Dr. Fawzi saying the '393 final
10:59:19 5 written decision from the PTAB is wrong because they looked
10:59:21 6 at the data wrong. That should come out. That's just
10:59:25 7 collateral estoppel independent of our summary judgment.
10:59:27 8 But those two issues are tied together.

10:59:30 9 THE COURT: Okay. Do you agree --

10:59:32 10 MR. BURROWBRIDGE: May I respond, Your Honor?

10:59:33 11 THE COURT: I'm sorry?

10:59:34 12 MR. BURROWBRIDGE: May I respond?

10:59:35 13 THE COURT: Yes.

10:59:36 14 MR. BURROWBRIDGE: So, Dr. Fawzi does not, I
10:59:38 15 believe, intend to opine that the '393 IPR was wrongly
10:59:44 16 decided.

10:59:45 17 THE COURT: Okay. Well, that's good because I
10:59:47 18 would exclude him from doing that.

10:59:48 19 MR. BURROWBRIDGE: Understood, Your Honor. So,
10:59:51 20 the analysis that Dr. Fawzi has done is a different
10:59:55 21 analysis. He looks at different data, and he does a unique
10:59:57 22 analysis tied to the claims asserted in this case.

10:59:59 23 THE COURT: Well, so what Mr. Sukduang just
11:00:01 24 said, I think, was it's relevant to the collateral estoppel
11:00:07 25 issue. I think what I understood him to be saying, it's not

11:00:12 1 actually relevant to any other issue.

11:00:15 2 Do you agree with that?

11:00:16 3 MR. BURROWBRIDGE: I don't agree with that. No,
11:00:18 4 Your Honor.

11:00:19 5 MR. SUKDUANG: So, then that raises the issue,
11:00:20 6 Your Honor, with respect to the '393 in their first motion.
11:00:23 7 Because if you look at Dr. Fawzi's expert report, the
11:00:26 8 paragraphs we pointed to, 100 to 114, he said expressly in
11:00:32 9 his expert report, Dr. Williams, who was a '393 declarant,
11:00:38 10 had data that Dr. Williams analyzed and that the '393 panel
11:00:45 11 at the PTAB considered. I'm now -- and the '393 was
11:00:50 12 invalidated.

11:00:51 13 I'm now taking that exact same data, and he
11:00:54 14 testified to that, because I made sure it's the exact same
11:00:57 15 data. Mr. Burrowbridge says it's different data. It's not.
11:01:00 16 It's the same data.

11:01:01 17 What Dr. Fawzi does is try to create a different
11:01:05 18 analysis on that exact same data, and that is expressed in
11:01:10 19 his report and expressed in his deposition. And his report
11:01:13 20 expressly says the '393 decision was wrong.

11:01:17 21 THE COURT: Well, no. He says that, and I did
11:01:27 22 actually read Paragraphs 98 to 114 or whatever exactly it
11:01:34 23 was trying to figure out what the context for this dispute
11:01:44 24 was, because it wasn't really clear to me. But so,
11:01:52 25 Dr. Fawzi, what is the point of this testimony that's at the

11:02:00 1 paragraphs which you say has some purpose other than on
11:02:04 2 collateral estoppel, what is the purpose?

11:02:07 3 MR. BURROWBRIDGE: Two points, Your Honor.
11:02:10 4 First, Dr. Fawzi's responding to Dr. Winkler. Dr. Winkler
11:02:14 5 has put forth these opinions. I hear counsel saying, for
11:02:19 6 purposes of collateral estoppel, I think that's correct.
11:02:22 7 But our concern, Your Honor, is that he will also use these
11:02:25 8 opinions to support their on-sale bar theory that they have.

11:02:28 9 MR. SUKDUANG: We don't have an on-sale bar
11:02:31 10 theory. There is no on-sale bar theory pleaded at all. I
11:02:33 11 don't know where that's coming from.

11:02:34 12 THE COURT: Okay. Well, in any event, there is
11:02:36 13 no on-sale bar theory, so good. Is there still a problem
11:02:42 14 here that I need to address?

11:02:44 15 MR. BURROWBRIDGE: Well, that's nice to hear as
11:02:45 16 well, yes. No on-sale bar theory, that's great.

11:02:48 17 The other issue is that they're putting -- Your
11:02:51 18 Honor, they're putting forward the same prior art references
11:02:54 19 that were litigated in the '393 IPR. And in doing so, their
11:02:59 20 expert, Dr. Winkler, has gone back into the data that was
11:03:04 21 used in the '393 IPR, and he's criticized the data there.
11:03:08 22 Dr. Fawzi does, in fact, use different data in this case.
11:03:12 23 It's in his expert report. It's not --

11:03:14 24 THE COURT: Wait, wait, wait, wait. Sorry,
11:03:16 25 Mr. Burrowbridge. I'm starting to lose the thread of what

11:03:19 1 | you're saying.

11:03:22 2 Is it the case -- and it's called Dr. Fawzi's
11:03:26 3 rebuttal expert report, so I take it this has nothing to do
11:03:30 4 with infringement; right?

11:03:32 5 MR. BURROWBRIDGE: Correct, Your Honor.

11:03:33 6 THE COURT: Okay. And so, it's rebutting a
11:03:38 7 report that has been filed in this case by which expert of
11:03:43 8 the Defendants?

11:03:43 9 MR. BURROWBRIDGE: Dr. Winkler.

11:03:46 10 THE COURT: Okay. And Dr. Winkler's specific
11:03:54 11 opinion that he's rebutting here is -- and I say specific.
11:03:58 12 It may not be. It may be hard to actually say specifically
11:04:01 13 what it is, but what's the general gist of the Winkler
11:04:04 14 opinion that he's rebutting?

11:04:06 15 MR. BURROWBRIDGE: The general gist of the
11:04:07 16 opinion is that the '393 IPR got it right.

11:04:14 17 THE COURT: Okay. Well --

11:04:15 18 MR. BURROWBRIDGE: And --

11:04:15 19 THE COURT: -- so I'm not going to let him
11:04:17 20 testify that the '393 IPR got it right.

11:04:19 21 MR. BURROWBRIDGE: Okay.

11:04:19 22 THE COURT: I understand maybe that's just a
11:04:21 23 shorthand for saying he's going to say -- was he a witness
11:04:25 24 in the '393 IPR?

11:04:27 25 MR. SUKDUANG: Yes.

11:04:28 1 MR. BURROWBRIDGE: He was, Your Honor, but let
11:04:29 2 me try to explain. So, what Dr. Winkler opines is that the
11:04:33 3 same prior art references that were asserted in the '393 IPR
11:04:37 4 also anticipate the patent in the '066 patent in this case
11:04:42 5 and the product in this case.

11:04:44 6 THE COURT: Okay.

11:04:44 7 MR. BURROWBRIDGE: And so, we are concerned that
11:04:46 8 he is going to use those opinions to bolster a -- I don't
11:04:52 9 know. I'm not sure if they're running an anticipation
11:04:55 10 theory or an obvious theory based on the publications, so
11:04:58 11 it's not just for collateral estoppel purposes. And what
11:05:02 12 Dr. Fawzi has done is looked at a different set of data
11:05:06 13 explicitly. Since there seems to be a dispute on this, he
11:05:09 14 looked at 163 batches, which the '393 patent looked at 178
11:05:14 15 batches. He ran a different statistical analysis that
11:05:16 16 Dr. Winkler didn't contest. And he's done that for purposes
11:05:20 17 of looking at whether or not that analysis supports unique
11:05:24 18 limitations in the claims at issue in this case.

11:05:29 19 THE COURT: Okay.

11:05:30 20 MR. SUKDUANG: So, can I address that? So,
11:05:31 21 Mr. Burrowbridge seems to profess confusion as to the
11:05:35 22 defenses. We have the Pretrial Order. I think that's a red
11:05:39 23 herring on Mr. Burrowbridge's part. The Pretrial Order is
11:05:41 24 there, and it clearly says what it is. The '393 issue,
11:05:45 25 you've ruled on that. Dr. Fawzi should not be able to opine

11:05:50 1 on that because you said Dr. Winkler can't opine on that.

11:05:53 2 The other issue is the '066 is a
11:05:56 3 product-by-process claim. A product-by-process claim is
11:05:59 4 only valid if the product is new or non-obvious. That issue
11:06:08 5 is addressed by Dr. Winkler. The data to show that the
11:06:13 6 product of the '393, excuse me, of the '066 is the same as
11:06:17 7 the prior art and not the prior art references that
11:06:22 8 Mr. Burrowbridge presents, but the actual API that UTC made
11:06:27 9 previously that it is not new or novel over that. UTC told
11:06:32 10 the FDA that that product of the '066 is the same as the
11:06:36 11 product from what they did in their prior plant. And we're
11:06:40 12 using that statement and the data that UTC analyzed to come
11:06:46 13 to that conclusion for Dr. Winkler to say that the product
11:06:51 14 of the '066 is the same as the prior art product. And,
11:06:56 15 therefore, the product-by-process claim of the '066 is
11:07:01 16 invalid because --

11:07:02 17 THE COURT: I'm sorry. What is the prior art
11:07:04 18 product?

11:07:05 19 MR. SUKDUANG: The prior art is the made
11:07:09 20 trepostinil API by UTC. It's not a prior art reference.
11:07:13 21 It's the prior art product.

11:07:19 22 And so, on a product by process, if the product
11:07:21 23 is not new or novel --

11:07:23 24 THE COURT: Wait, wait.

11:07:37 25 MR. BURROWBRIDGE: Your Honor, if I may?

11:07:39 1 THE COURT: Wait, wait, wait. So, if the '393
11:07:53 2 patent is not prior art, isn't it the case that the
11:07:59 3 trepostinil that it's made by is not prior art?

11:08:02 4 MR. SUKDUANG: No, that's incorrect. The '393
11:08:04 5 is the same continuation as the '066 and the '901. It's the
11:08:08 6 same family.

11:08:08 7 THE COURT: Yes.

11:08:09 8 MR. SUKDUANG: So, it's not prior art. But the
11:08:11 9 product -- so, UTC has been making trepostinil since 2000.
11:08:16 10 The '393 patent doesn't come up until 2006.

11:08:19 11 THE COURT: Well, so the trepostinil you're
11:08:22 12 saying is the same as your --

11:08:28 13 MR. SUKDUANG: The '066.

11:08:30 14 THE COURT: As I guess what you get from the
11:08:33 15 '066 patent. You're going to say here's something from 2000
11:08:37 16 and it's so and so?

11:08:39 17 MR. SUKDUANG: Right. It has nothing to do with
11:08:41 18 the '393. The '066 and the '393 --

11:08:44 19 THE COURT: Okay. Okay. Hold on.

11:09:07 20 All right. Mr. Burrowbridge.

11:09:07 21 MR. BURROWBRIDGE: Your Honor, counsel just
11:09:09 22 stood in court and said they are not running an on-sale bar
11:09:13 23 theory. What he described just now is an on-sale bar
11:09:15 24 theory.

11:09:15 25 THE COURT: Well, he must have some other theory

11:09:17 1 because, yes, he said he is not doing an on-sale bar theory
11:09:20 2 or he said he's not. I mean, I think he's -- so, I mean --

11:09:28 3 MR. BURROWBRIDGE: Your Honor --

11:09:29 4 THE COURT: -- if, in fact, the product was
11:09:32 5 known, it doesn't really matter whether it was on sale or
11:09:35 6 not; right?

11:09:35 7 MR. SUKDUANG: Correct, Your Honor.

11:09:37 8 MR. BURROWBRIDGE: Your Honor, first of all,
11:09:40 9 they need to prove all of that up and --

11:09:42 10 THE COURT: Well, no, no. We're talking like
11:09:44 11 these people are going to prove this stuff.

11:09:46 12 MR. BURROWBRIDGE: Okay. Well, let's just
11:09:47 13 assume that's the case. Let's assume that that's their
11:09:49 14 theory, then Dr. Fawzi should be able to analyze the data
11:09:52 15 and say that the data on the claimed product of the '066
11:09:56 16 patent, which has unique limitations in this case, is
11:09:58 17 different than that prior art product.

11:10:02 18 THE COURT: Okay. So, what's wrong with that,
11:10:05 19 Mr. Sukduang?

11:10:05 20 MR. SUKDUANG: Because the data that Dr. Fawzi
11:10:08 21 relies on, and Mr. Burrowbridge says he reviews fewer
11:10:13 22 batches, and in fact, those batches were actually excluded
11:10:17 23 by the PTAB as well. So, they reviewed the same number, the
11:10:20 24 same batches Dr. Williams, Dr. Fawzi. They reviewed the
11:10:24 25 same number of batches.

11:10:25 1 So, what Dr. Fawzi is doing is saying -- and
11:10:28 2 that issue, what that data shows has already been decided.
11:10:33 3 Dr. Fawzi is now trying to say that data that has already
11:10:35 4 been decided, what it shows and doesn't show, somebody got
11:10:39 5 it wrong. They should have looked at it this way instead of
11:10:42 6 that way. And not somebody, UTC. UTC litigated the '393.
11:10:48 7 It's not some other party.

11:10:49 8 So, if they believed back in the '393 that the
11:10:52 9 data should have been reviewed a certain way, they forego
11:10:56 10 that right. And so, the issue is Dr. Fawzi is looking at
11:11:01 11 the same data that was actually considered and relied upon
11:11:04 12 by the PTAB to come up with a different argument on the same
11:11:10 13 data to come up with a different conclusion than what that
11:11:14 14 data, what factually that data has shown by the PTAB and the
11:11:20 15 Federal Circuit. That's collateral estoppel.

11:11:22 16 THE COURT: Yeah, at the PTAB, somebody was
11:11:25 17 comparing the product, the prior art trepostinil and what
11:11:32 18 was produced according to the '393 patent; right?

11:11:35 19 MR. SUKDUANG: Correct.

11:11:35 20 THE COURT: So, this is being produced by the
11:11:39 21 '066 patent; right?

11:11:41 22 MR. SUKDUANG: No. The data that Dr. Fawzi
11:11:45 23 relies on is not the '393 data. The data Dr. Fawzi looks at
11:11:51 24 is the data from 2000.

11:11:54 25 THE COURT: Yes, and comparing it to what?

11:11:57 1 MR. SUKDUANG: Comparing it to the '066. So,
11:11:59 2 the issue is not what did -- Dr. Fawzi's analysis is not
11:12:02 3 what the '066 does. It's what this other data that was
11:12:05 4 already considered that doesn't change between '393 and
11:12:10 5 '066, because that's static. What Dr. Fawzi is trying to
11:12:14 6 say is this data from 2000 should have been looked at
11:12:19 7 differently when you look at the '066.

11:12:21 8 And when he says that, he says it's the same
11:12:24 9 issue that the PTAB got wrong for the '393. So, we're not
11:12:27 10 challenging Dr. Fawzi from saying anything about the '066
11:12:31 11 product. He can do that.

11:12:33 12 What we're challenging is that what the data
11:12:37 13 shows from 2000, that's static. That already was decided by
11:12:43 14 the PTAB and the Federal Circuit. That's the issue that we
11:12:47 15 have with it. He can say whatever he wants about
11:12:50 16 differences in the '066 and the claims, and whatever he
11:12:52 17 wants, he can say.

11:12:54 18 But what he should be estopped from doing is
11:12:56 19 saying that data from 2000 should be looked at differently.
11:13:00 20 And when you look at that data differently, and you look at
11:13:03 21 the '066, you get a different result. And --

11:13:07 22 THE COURT: And your argument on this is it's
11:13:10 23 not like, you know, before he was or somebody for UTC was
11:13:20 24 looking at the data and saying, you know, it has this
11:13:26 25 excipient in it, and now he's looking at the data and saying

11:13:30 1 it has that excipient in it. He's basically looking at the
11:13:36 2 same thing that the PTAB said was 99 point whatever
11:13:41 3 percentage and saying it's, instead of being 99.7, it's 99.5
11:13:49 4 or something like that; right?

11:13:50 5 MR. SUKDUANG: Right. It's purity. So, the
11:13:52 6 issue before the PTAB was purity. How pure or impure the
11:13:56 7 prior --

11:13:56 8 THE COURT: Pure. And what you're talking about
11:13:58 9 here, and I'm sorry to keep interrupting --

11:14:00 10 MR. SUKDUANG: Sure.

11:14:00 11 THE COURT: -- is the purity of the prior art
11:14:04 12 for trepostinil?

11:14:06 13 MR. SUKDUANG: Correct. So, the issue, the
11:14:07 14 fundamental issue that UTC has presented is whether it's a
11:14:12 15 '393 or it's --

11:14:13 16 THE COURT: And I'm sorry, because I know you're
11:14:17 17 trying to help here, but it's relevant to obviousness or
11:14:29 18 possibly anticipation as to what the purity of the prior art
11:14:36 19 trepostinil was?

11:14:37 20 MR. SUKDUANG: What the purity and the nature of
11:14:40 21 the prior art trepostinil product was, and I'm going to use
11:14:44 22 the word 2000, but it spans from 2000 to the --

11:14:46 23 THE COURT: Yes.

11:14:47 24 MR. SUKDUANG: So, 2000. If the '066 product,
11:14:51 25 the product-by-process claim, if the product of that

11:14:54 1 product-by-process claim is the same as that prior art
11:14:59 2 product, then the product-by-process claim is invalid. It
11:15:03 3 doesn't have to be on sale or whatnot.

11:15:06 4 THE COURT: Okay. And so, your position, which
11:15:12 5 I take it maybe is part of what you're going to be arguing
11:15:15 6 in front of Judge Hall, is that because the calculation of
11:15:22 7 the purity of the prior art trepostinil was presented to the
11:15:30 8 PTAB, the PTAB put a number in its opinion saying, We rule
11:15:34 9 as "X". The case got affirmed by the Federal Circuit that
11:15:40 10 the purity of the trepostinil and the prior art product is
11:15:47 11 essentially a fact that cannot be changed?

11:15:50 12 MR. SUKDUANG: Correct. And that's the
11:15:52 13 collateral estoppel, and that's what Dr. Fawzi is trying to
11:15:55 14 change.

11:15:55 15 THE COURT: Okay. Mr. Burrowbridge, did I more
11:16:02 16 or less -- my understanding of what they were just arguing,
11:16:08 17 is that your understanding, too?

11:16:09 18 MR. BURROWBRIDGE: Of what they're arguing?

11:16:12 19 THE COURT: Yes.

11:16:14 20 MR. BURROWBRIDGE: I don't think it fairly
11:16:16 21 characterizes what Dr. Fawzi's opinions are, and I don't
11:16:19 22 think it fairly characterizes the scope of the paragraphs
11:16:23 23 they're trying to exclude.

11:16:24 24 THE COURT: Well, so that's a slightly different
11:16:25 25 question.

11:16:27 1 MR. BURROWBRIDGE: Understood.

11:16:27 2 THE COURT: So, let me just try phrasing it
11:16:30 3 slightly different. Do you agree that somebody for UTC put
11:16:37 4 forth an expert opinion about what the purity of the prior
11:16:45 5 art trepostinil was in connection with the validity or
11:16:49 6 invalidity of the '393 patent?

11:16:52 7 MR. BURROWBRIDGE: With regard to that question,
11:16:55 8 yes, with regard to the validity of the '393 patent, but
11:16:58 9 there were different limitations at issue there.

11:17:01 10 THE COURT: Right. And the scientific
11:17:10 11 conclusion of the purity, that was accepted by the PTAB.
11:17:21 12 And I haven't looked at the Federal Circuit's opinion, if
11:17:26 13 there was even an opinion, but that's a fact that, at a
11:17:35 14 minimum, went into the PTAB's analysis of why it reached the
11:17:39 15 result it did on the '393 patent; right?

11:17:42 16 MR. BURROWBRIDGE: Yes, Your Honor.

11:17:44 17 THE COURT: Okay. And what Dr. Fawzi does is,
11:17:52 18 in terms of the purity of the prior art process, he now says
11:17:58 19 something different than what the PTAB concluded in its
11:18:05 20 opinion; is that right?

11:18:08 21 MR. BURROWBRIDGE: Well, I'm not sure that it's
11:18:11 22 the right question, so it's difficult to answer.

11:18:12 23 THE COURT: Okay. Well, so answer my
11:18:14 24 question --

11:18:15 25 MR. BURROWBRIDGE: I will try.

11:18:15 1 THE COURT: -- if you can, and then you can tell
11:18:17 2 me what the question should be.

11:18:18 3 MR. BURROWBRIDGE: Okay. Well, I think my
11:18:20 4 answer has to be, no, because Dr. Fawzi's not analyzing the
11:18:24 5 data with regard to a purity limitation. There's no purity
11:18:28 6 limitation in the '066 patent asserted in this case.

11:18:30 7 THE COURT: So, why did he do this?

11:18:33 8 MR. BURROWBRIDGE: Well, Your Honor, that's not
11:18:34 9 what Dr. Fawzi is doing. Dr. Fawzi is rebutting
11:18:36 10 Dr. Winkler's --

11:18:38 11 THE COURT: But, okay. You go ahead. Maybe
11:18:40 12 you're getting to -- maybe I'm misunderstanding what you're
11:18:44 13 saying.

11:18:44 14 MR. BURROWBRIDGE: So, there are a few issues,
11:18:46 15 but I'll try to get through them. First of all, they never
11:18:49 16 disclosed this collateral estoppel theory. When they put it
11:18:52 17 in their expert report or when they put it in an analysis of
11:18:54 18 the batch data, the batch-to-batch data, our expert
11:18:59 19 responded to that analysis.

11:19:02 20 The analysis, as Dr. Fawzi uses it in his
11:19:06 21 opinions, is to bolster his opinion that the unique
11:19:12 22 limitations in the asserted patent, such as specific
11:19:17 23 impurities lowering, and a trepostinil sodium salt that is
11:19:24 24 stable at any temperature can be proved on the data that
11:19:27 25 he's analyzed in rebutting Dr. Winkler. That's an analysis

11:19:31 1 that's never been done before. It's not been done by --

11:19:34 2 THE COURT: But the premise of it or in the
11:19:40 3 results he gets, it's fair to say, even if that analysis
11:19:49 4 hadn't been done before, it is inconsistent, isn't it, with
11:19:53 5 the analysis that has been done before because when he does
11:20:00 6 what he does, he comes up with a different number for purity
11:20:04 7 than what was come up with before.

11:20:07 8 MR. BURROWBRIDGE: I don't believe it's
11:20:08 9 inconsistent at all, Your Honor.

11:20:09 10 THE COURT: Why not?

11:20:10 11 MR. BURROWBRIDGE: The '393 IPR looked at a set
11:20:12 12 of data that a prior expert had put forth to the '393
11:20:17 13 patent. And the panel criticized some of that data and said
11:20:22 14 for purposes of the validity question going on in the '393,
11:20:25 15 this data is not helpful.

11:20:27 16 Dr. Fawzi is looking at a different set of data.
11:20:30 17 He reduces the batches from 178 to 163, and in doing so,
11:20:35 18 he's able to account for batch-to-batch variation that
11:20:40 19 otherwise wasn't accounted for. And he opines specifically
11:20:44 20 on more than just purity, which was what was at issue in the
11:20:47 21 '393.

11:20:47 22 THE COURT: Right, right. But, in other words,
11:20:53 23 and so that's kind of what I'm trying to understand which
11:20:59 24 is, for example, let's say in the PTAB proceeding, the PTAB
11:21:12 25 said the overall purity is 99.7 percent. And Dr. Fawzi now

11:21:20 1 says, Well, I'm going to do something different. I'm going
11:21:22 2 to break it into five subsets. And when I break it into
11:21:26 3 five subsets, I get this, and this, and this. And by the
11:21:29 4 way, this analysis corresponds with an overall purity of
11:21:34 5 99.5 percent.

11:21:40 6 Is that analogous to what's actually happening
11:21:44 7 here?

11:21:44 8 MR. BURROWBRIDGE: I think it is close, but the
11:21:49 9 problem with it is that Dr. Winkler has done an analysis
11:21:53 10 that's different than what the Board did. And then
11:21:57 11 Dr. Fawzi is rebutting that analysis.

11:22:00 12 THE COURT: Okay.

11:22:01 13 MR. BURROWBRIDGE: And so, in rebutting
11:22:03 14 Dr. Winkler's analysis, which is Liquidia's expert,
11:22:08 15 Dr. Fawzi is looking at a different set of data, and he's
11:22:12 16 looking at a unique question of validity relating to
11:22:17 17 specific limitations not otherwise previously litigated.

11:22:21 18 THE COURT: All right. So --

11:22:22 19 MR. BURROWBRIDGE: So --

11:22:22 20 THE COURT: -- go ahead. I'm sorry. Go ahead.

11:22:25 21 MR. BURROWBRIDGE: Just a quick point. The
11:22:26 22 purity that was the focus in the '393 is not what the focus
11:22:31 23 is in this case.

11:22:32 24 THE COURT: All right. So, Mr. Sukduang, the --

11:22:37 25 MR. SUKDUANG: The different analysis issue with

11:22:38 1 Dr. Winkler?

11:22:39 2 THE COURT: Yes.

11:22:40 3 MR. SUKDUANG: He doesn't. He takes --
11:22:43 4 Dr. Fawzi says in his expert report, Paragraph 101,
11:22:45 5 "Dr. Winkler adopts the panel's scientifically unsound
11:22:48 6 reasoning that occasional outlier batches can pass
11:22:53 7 impurity."

11:22:53 8 THE COURT: So, ignore for a minute what their
11:22:56 9 expert characterizes what your expert did. Did your expert
11:23:01 10 just say, Here's a copy of the opinion; my job is? Done.

11:23:04 11 MR. SUKDUANG: Dr. Winkler did two things. He
11:23:06 12 said this issue, this purity issue on the 2000 batches was
11:23:10 13 considered by the Patent Office. Okay. I went to look at
11:23:14 14 the data, I, Dr. Winkler, went to look at the data. He was
11:23:20 15 involved in that case. Went to look at the data that UTC's
11:23:25 16 expert relied upon, Dr. Williams.

11:23:27 17 Dr. Williams passed away, so that's why he's not
11:23:30 18 here. Dr. Williams looked at a certain number of batches.
11:23:33 19 During Dr. Williams' deposition, Dr. Williams conceded that
11:23:37 20 several of those batches should not have been considered.

11:23:40 21 Okay. The PTAB took that opinion, Dr. Williams'
11:23:44 22 opinion. Also looked at his deposition testimony where he
11:23:47 23 said certain of these batches should not have been
11:23:49 24 considered because they're developmental, not the process
11:23:51 25 that UTC actually follows, and here's the purity of it.

11:23:57 1 Dr. Winkler looked at that exact same data,
11:24:01 2 takes out the batches that Dr. Williams testified shouldn't
11:24:04 3 have been looked at, that the PTAB said shouldn't have been
11:24:07 4 looked at and says, Okay, here's what the data shows.
11:24:10 5 Here's the purity. That is the static nature of the 2000
11:24:15 6 data.

11:24:18 7 Dr. Fawzi then looks at Dr. Winkler's opinion in
11:24:21 8 this case. Dr. Winkler says, You should not look at these
11:24:25 9 batches. Dr. Fawzi says, Okay, I'm not going to look at
11:24:28 10 these batches.

11:24:29 11 That issue about the different data is expressed
11:24:32 12 in the '393 final written decision where the PTAB itself
11:24:37 13 said, If you take out this data, which Dr. Williams says you
11:24:41 14 don't need to look at, here's the conclusion. Dr. Winkler
11:24:45 15 did that here in this case. Dr. Fawzi did that here in this
11:24:49 16 case.

11:24:51 17 Dr. Winkler says, Here's what the PTAB found and
11:24:54 18 here's my review of it. Dr. Fawzi says, Oh, no, you need to
11:24:58 19 do a different calculation on that same --

11:25:01 20 THE COURT: Well, so, I don't understand how or
11:25:04 21 I'm having trouble understanding how Dr. Winkler can review
11:25:08 22 the PTAB's work and express opinions, and if he does that,
11:25:14 23 why they can't have somebody review the PTAB's work and
11:25:18 24 express opinions.

11:25:19 25 MR. SUKDUANG: So, that's why there's two

11:25:21 1 issues. The '393, you got rid of. That's part one of
11:25:24 2 Dr. Winkler's opinion. You said you can't talk about '393.

11:25:27 3 THE COURT: Okay.

11:25:28 4 MR. SUKDUANG: That's gone. What Dr. Winkler
11:25:30 5 does, and we anticipate because they raised this issue,
11:25:32 6 okay, if that goes away, there's still the underlying data.
11:25:37 7 There's still the underlying data from the 2000 batches that
11:25:42 8 Dr. Winkler looks at and makes his analysis on completely
11:25:49 9 independent of what happened at the PTAB. But the
11:25:52 10 scientific data is there.

11:25:55 11 THE COURT: So, if he did that, can't their
11:25:58 12 expert do that, too?

11:25:59 13 MR. SUKDUANG: No, because it's the same because
11:26:02 14 UTC is now taking that same data that Dr. Winkler's looking
11:26:06 15 at. Dr. Winkler reaches the conclusion. Dr. Fawzi's now
11:26:11 16 saying that exact same data reaches a different conclusion.
11:26:15 17 That's collateral estoppel.

11:26:17 18 THE COURT: But I don't understand how if your
11:26:20 19 guy has to do an analysis to come up with something, then it
11:26:27 20 seems like there is something happening more than just
11:26:32 21 saying this has already been decided.

11:26:35 22 MR. SUKDUANG: The analysis that Dr. Winkler
11:26:37 23 does is the analysis that Dr. Williams does, UTC's expert,
11:26:40 24 the analysis that UTC did, the analysis that the PTAB did.
11:26:44 25 But because of these issues of whether you can rely on the

11:26:49 1 '393 or not, he still has to independently do that.

11:26:52 2 What Dr. Winkler did --

11:26:54 3 THE COURT: Well, so, isn't that then -- if it
11:27:02 4 turns out he doesn't have to -- if it turns out he can rely
11:27:06 5 on the '393, which I take it is what Judge Hall is going to
11:27:09 6 decide, then it doesn't matter. It's only if he can't rely
11:27:16 7 on that in which case then it seems like they ought to be
11:27:19 8 able to counter what he says.

11:27:22 9 Right?

11:27:23 10 MR. SUKDUANG: No. If Dr. Winkler says that the
11:27:26 11 purity is 99.7, and the PTAB looked at that data and said
11:27:30 12 the purity is 99.7, and UTC looked at that data back in the
11:27:36 13 '393 and said the purity is 99.7, Dr. Fawzi can't look at
11:27:41 14 the same data and say, Oh, the purity is 90 or the purity is
11:27:44 15 a hundred. That's the issue. He can't take the same data
11:27:48 16 and reach a conclusion on that data that was already decided
11:27:53 17 against UTC.

11:27:58 18 And that's what he does because he says the
11:28:01 19 Patent Office was wrong. They should have looked at it this
11:28:04 20 way.

11:28:05 21 THE COURT: Yeah, yeah. So, okay. I think
11:28:06 22 we've probably reached the limits of what is useful argument
11:28:12 23 here today.

11:28:13 24 MR. BURROWBRIDGE: Your Honor, may I make one
11:28:14 25 point --

11:28:15 1 THE COURT: Go ahead.

11:28:16 2 MR. BURROWBRIDGE: -- quickly? I will be quick.

11:28:17 3 Counsel just said that Dr. Winkler did the same
11:28:20 4 analysis that Dr. Williams did. That's not accurate. He
11:28:23 5 did not do the same analysis that Dr. Williams did. He did
11:28:26 6 an analysis based on what the IPR did. The issue about
11:28:30 7 whether or not the larger scope of batches should be
11:28:34 8 considered or the more narrow scope of batches should be
11:28:36 9 considered has never been fully and fairly litigated,
11:28:39 10 certainly not on this patent and these claims.

11:28:41 11 THE COURT: Okay. So, thank you,
11:28:44 12 Mr. Burrowbridge.

11:28:44 13 So, on this Defendant's motion in limine Docket
11:28:53 14 Item 320, Dr. Fawzi may not opine that the PTAB got the
11:29:00 15 invalidity decisions of the '393 patent wrong or that there
11:29:06 16 are "clear errors" in the '393 IPR panel's conclusions as
11:29:16 17 has been discussed here, there's quite a few different
11:29:20 18 paragraphs in Dr. Fawzi's expert report that are mentioned
11:29:24 19 in the Defendant's briefing. It was not clear to me from
11:29:29 20 the briefing how much more the Defendant was trying to limit
11:29:42 21 Dr. Fawzi.

11:29:44 22 There's a lot of factual disputes about exactly
11:29:52 23 what's happening that's been said by one side or the other
11:29:57 24 this morning. And the Magistrate Judge's decision on the
11:30:04 25 pending motion for summary judgment, which is Docket

11:30:06 1 Item 281, may be helpful, may need to be considered before I
11:30:17 2 reach any further conclusion. So, as far as that part of
11:30:26 3 Defendant's motion in limine goes, it's granted in part and
11:30:30 4 it's left open in part.

11:30:35 5 There was a different dispute, a secondary
11:30:38 6 dispute in Defendant's motion in limine, which I will
11:30:44 7 summarize as the Defendant saying Dr. Fawzi's opinions
11:30:50 8 involving column chromatography are "nonsensical" which
11:30:59 9 appears to be related to validity or invalidity challenges
11:31:03 10 to the '066 and '901 patents. And I think whether or not
11:31:12 11 Dr. Fawzi's opinions are nonsensical is something best
11:31:16 12 handled by cross-examination and or opposing testimony from
11:31:21 13 Defendant's experts. So, I'm going to deny that part of the
11:31:24 14 motion.

11:31:25 15 Anything else?

11:31:31 16 MR. SUKDUANG: Nothing from Defendants, Your
11:31:33 17 Honor.

11:31:33 18 MR. BURROWBRIDGE: Thank you.

11:31:34 19 THE COURT: All right. And just in connection
11:31:42 20 with the trial, the Pretrial Order or anything else,
11:31:50 21 everybody's satisfied we've resolved, to the best we can,
11:31:53 22 what we need to resolve this morning?

11:31:55 23 MR. JACKSON: As far as we are, Plaintiffs are
11:31:57 24 concerned, yes, Your Honor. Thank you.

11:31:58 25 MR. SUKDUANG: Yes, Your Honor. Thanks.

11:32:00 1 THE COURT: Okay. All right.

11:32:10 2 I guess I should ask this, though it seems
11:32:13 3 unlikely to me: Is there any possibility of the parties
11:32:18 4 resolving this dispute short of trial?

11:32:20 5 MR. JACKSON: I will tell you that the parties
11:32:23 6 have communicated about settlement at various points. I
11:32:27 7 think it's very unlikely it will resolve before trial starts
11:32:30 8 on March 28th.

11:32:31 9 THE COURT: Okay. All right. Thank you.

11:32:33 10 All right. Once I have the Magistrate Judge's
11:32:41 11 decision on the pending summary judgment motion, I may try
11:32:50 12 to see whether that helps me any in terms of deciding what
11:32:57 13 to do about Dr. Fawzi about the thing we just spent time
11:33:01 14 discussing. But my default is that if I'm not clear, I'm
11:33:10 15 going to let him testify. And to the extent I'm going to
11:33:34 16 let him testify about his analysis of the data. And it may
11:33:42 17 turn out to be that the subject of whether what he's doing
11:33:46 18 is barred by collateral estoppel or not is something that I
11:33:51 19 will decide after I hear what it is because it seems very
11:33:58 20 complex. But if I get any further insight on it between now
11:34:15 21 and the trial, I will let you know.

11:34:19 22 Okay? So, thank you for your -- oh, and so,
11:34:27 23 Mr. Flynn, in terms of -- I think it would be good for the
11:34:34 24 parties to try to put these rulings or whatever it is that
11:34:44 25 I've said into the Pretrial Order. And to the extent the

11:34:56 1 Pretrial Order has argument about things that are being
11:34:58 2 decided by Judge Hall or by me later on on objections to
11:35:06 3 Judge Hall, you know, identify that as an issue or problem
11:35:10 4 with a motion or whatever it is, but not to have the legal
11:35:13 5 argument in the Pretrial Order.

11:35:15 6 MR. FLYNN: Understood, Your Honor.

11:35:17 7 THE COURT: Okay. So, it may take -- do you
11:35:20 8 think the parties can meet, confer and figure this out by,
11:35:24 9 say, the end of next week?

11:35:26 10 MR. FLYNN: I think so, Your Honor. I think the
11:35:27 11 transcript will be very helpful in getting that done.

11:35:30 12 THE COURT: Okay. Well, thank you everyone for
11:35:32 13 your time today. We'll be in recess.

11:35:34 14 DEPUTY CLERK: All rise.

15 (Court was recessed at 11:35 a.m.)

16 I hereby certify the foregoing is a true and
17 accurate transcript from my stenographic notes in the
18 proceeding.

19 /s/ Heather M. Triozzi
20 Certified Merit and Real-Time Reporter
21 U.S. District Court
22
23
24
25

EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS)	
CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 20-755-RGA-JLH
)	
LIQUIDIA TECHNOLOGIES, INC.,)	
)	
Defendant.)	

**DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S
NOTICE OF SUBSEQUENT AUTHORITY**

OF COUNSEL:
Sanya Sukduang
Jonathan Davies
Douglas W. Cheek
COOLEY LLP
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004-2400
(202) 842-7800

Erik Milch
COOLEY LLP
11951 Freedom Drive, 14th Floor
Reston, VA 20190-5640
(703) 546-8000

Ivor Elrifi
COOLEY LLP
55 Hudson Yards
New York, NY 10001-2157
(212) 479-6000

Karen E. Keller (No. 4489)
Jeff Castellano (No. 4837)
David M. Fry (No. 5486)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
kkeller@shawkeller.com
jcastellano@shawkeller.com
dfry@shawkeller.com
nhoeschen@shawkeller.com
*Attorneys for Defendant Liquidia
Technologies, Inc.*

Deepa Kannappan
Lauren Krickl
Brittany Cazakoff
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
(650) 843-5000

Liquidia notifies the Court of the PTAB's Final Written Decision in the IPR of U.S. Patent No. 9,604,901 ("901 Patent"). (Exhibit 1.) The PTAB held claims 1–5, 8, and 9 of the '901 Patent as unpatentable as obvious over Moriarty and Phares and claims 6–7 patentable based on its construction of "storage," different from the Court's construction here. (Ex. 1 at 31–44, 46–50.) The PTAB construed several terms relevant to this case:

Term	UTC's Construction	Liquidia's Construction	PTAB's Construction
"(c) contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil"	Plain and ordinary meaning	"contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil, wherein the salt is formed without isolation of treprostinil after alkylation and hydrolysis" (D.I. 75 at 57–61, 64–67.)	Treprostinil is not isolated from the solution formed in step (b) before forming a salt in step (c). Ex. 1 at 25–28. The PTAB's construction supports the arguments offered by Liquidia at pages 57–61 and 64–67 of the joint claim construction brief. (D.I. 75.)
"pharmaceutical batch"	"a specific quantity of treprostinil (or its salt) that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture, wherein the uniform character and quality is such that it still contains impurities resulting from the method by which it is produced"	"pharmaceutical batch made according to the process recited in steps (a) – (d) and optionally (e), wherein no purification steps appear between alkylation and salt formation" (D.I. 75 at 47–51, 54–56.)	"Pharmaceutical batch" does not require storage stability. Ex. 1 at 18–20. The PTAB's construction supports the arguments offered by Liquidia at pages 47–51 and 54–56 of the joint claim construction brief. (D.I. 75.)

Term	UTC's Construction	Liquidia's Construction	PTAB's Construction
"storing" / "stored" / "storage"	"require that the stored material possesses stability sufficient to allow manufacture and which maintains integrity for a sufficient period of time to be useful for the preparation of a pharmaceutical composition or a pharmaceutical product"	The claim terms are indefinite (D.I. 36-40, 42-44.)	Actual storage for at least 3 months. Ex. 1 at 20-25. The PTAB's construction supports the arguments offered by Liquidia at pages 36-40 and 42-44 of the joint claim construction brief. (D.I. 75.)

OF COUNSEL:

Sanya Sukduang
Jonathan Davies
Douglas W. Cheek
COOLEY LLP
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004-2400
(202) 842-7800

Erik Milch
COOLEY LLP
11951 Freedom Drive, 14th Floor
Reston, VA 20190-5640
(703) 546-8000

Ivor Elrifi
COOLEY LLP
55 Hudson Yards
New York, NY 10001-2157
(212) 479-6000

Deepa Kannappan
Lauren Krickl
Brittany Cazakoff
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
(650) 843-5000

Dated: October 12, 2021

/s/ Nathan R. Hoeschen

Karen E. Keller (No. 4489)
Jeff Castellano (No. 4837)
David M. Fry (No. 5486)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
kkeller@shawkeller.com
jcastellano@shawkeller.com
dfry@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Defendant Liquidia Technologies, Inc.

IPR2020-00770
Patent 9,604,901 B2

I. INTRODUCTION

Liquidia Technologies, Inc. (“Petitioner”) filed a Petition (Paper 1 (“Pet.”)), seeking an *inter partes* review of claims 1–9 of U.S. Patent No. 9,604,901 B2 (Ex. 1001, “the ’901 patent”). We instituted trial to review the challenged claims. Paper 7 (“Dec.” or “Decision to Institute”). Thereafter, United Therapeutics Corporation (“Patent Owner”) filed a Response to the Petition (Paper 12, “PO Resp.”), Petitioner filed a Reply (Paper 15), and Patent Owner filed a Sur-reply (Paper 25).

The parties filed a Joint Paper Concerning Petitioner’s Request to Strike Portions of Patent Owner’s Paper Nos. 12 and 25 and Exhibits 2002 and 2025. Paper 29. The parties also briefed the issues of (1) whether we should exclude Exhibits 1002 and 1012 (Papers 31, 32, 37), and (2) whether Petitioner may submit, as supplemental information, the transcript and order from the *Markman* hearing in a parallel district court case (Papers 38, 40). An oral hearing for this proceeding was held on June 23, 2021, and the transcript of that hearing is of record. *See* Paper 44 (“Tr.”).

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons provided below, we conclude Petitioner has established by a preponderance of the evidence that claims 1–5, 8, and 9 are unpatentable. Petitioner, however, has not established by a preponderance of the evidence that claims 6 and 7 are unpatentable.

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A. The '901 Patent

The '901 patent relates to “an improved process to convert benzindene triol to treprostinil via salts of treprostinil and to purify treprostinil.”

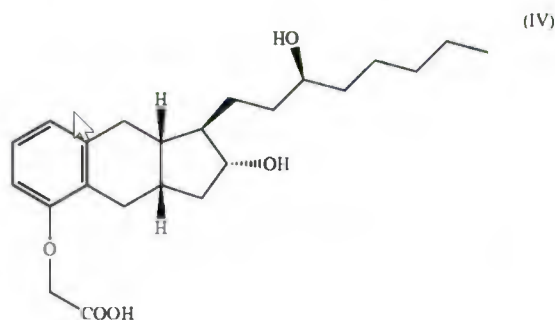
Ex. 1001, Abstract.

Prostacyclin derivatives are useful pharmaceutical compounds. *Id.* at 1:23–26. Treprostinil, a known prostacyclin derivative, is the active ingredient in Remodulin. *Id.* at 1:27–32. Before the '901 patent, treprostinil had been prepared as described in Moriarty¹ and other prior-art references. *Id.* According to the '901 patent, because treprostinil is “of great importance from a medicinal point of view, a need exists for an efficient process to synthesize th[is] compound[] on a large scale suitable for commercial production.” *Id.* at 1:66–2:3.

The '901 patent discloses “a process for the preparation of a compound having formula IV, or a hydrate, solvate, or pharmaceutically acceptable salt thereof.” *Id.* at 8:44–46. Petitioner represents that Formula IV is treprostinil. Pet. 11; Ex. 1002 ¶ 30. Formula IV has the following structure:

¹ Moriarty et al., The Intramolecular Asymmetric Pauson-Khand Cyclization as a Novel and General Stereoselective Route to Benzindene Prostacyclins: Synthesis of UT-15 (Treprostinil), 69 J. ORG. CHEM. 1890–1902 (2004) (Ex. 1009). Moriarty is one of the prior-art references asserted in this proceeding.

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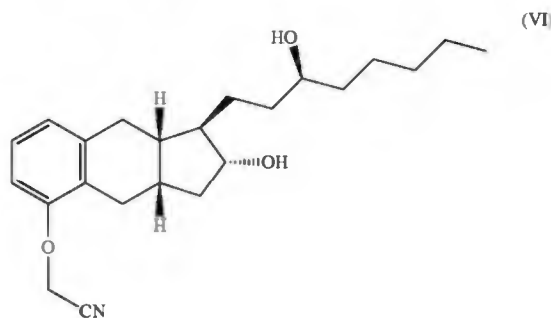
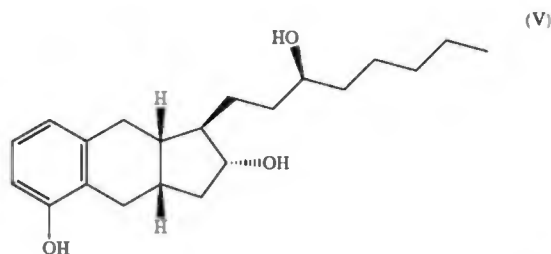


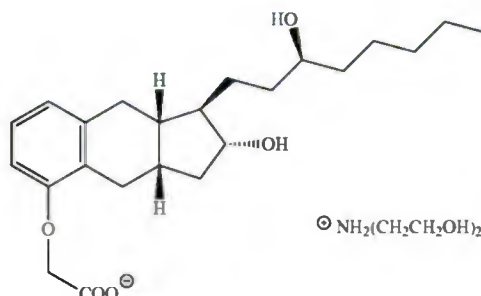
The figure above shows the structure of Formula IV. Ex. 1001,
 8:48–63.

The process of the '901 patent comprises

- alkylating a compound of structure V with an alkylating agent such as ClCH_2CN to produce a compound of formula VI,
- hydrolyzing the product of step (a) with a base such as KOH ,
- contacting the product of step (b) with a base B such as diethanolamine to form [sic] a salt of the following structure, and
- reacting the salt from step (b) with an acid such as HCl to form the compound of formula IV.

Id. at 8:65–9:48. Structure V, formula VI, and the salt formed in step (c) have the following structures:





The figures above show the structures of structure V, formula VI, and the salt formed in step (c). *Id.* at 9:1–28, 9:33–45. The '901 patent states that “[i]n one embodiment, the purity of compound of formula IV is at least 90.0%, 95.0%, 99.0%, 99.5%.” *Id.* at 9:49–50.

According to the '901 patent:

The quality of treprostnil produced according to this invention is excellent. The purification of benzindene nitrile by column chromatography is eliminated. The impurities carried over from intermediate steps (i.e. alkylation of triol and hydrolysis of benzindene nitrile) are removed during the carbon treatment and the salt formation step. Additional advantages of this process are: (a) crude treprostnil salts can be stored as raw material at ambient temperature and can be converted to treprostnil by simple acidification with diluted hydrochloric acid, and (b) the treprostnil salts can be synthesized from the solution of treprostnil without isolation. This process provides better quality of final product as well as saves significant amount of solvents and manpower in purification of intermediates.

Id. at 16:66–17:12, *see also id.* at 6:4–18 (the same).

B. Illustrative Claim

Claim 1 is the only independent claim. With the Certificate of Correction (Ex. 1006, 2) incorporated, it is reproduced below:

1. A pharmaceutical batch consisting of treprostinil or a salt thereof and impurities resulting from (a) alkylating a benzindene triol, (b) hydrolyzing the product of step (a) to form a solution

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comprising treprostinil, (c) contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil, (d) isolating the salt of treprostinil, and (e) optionally reacting the salt of treprostinil with an acid to form treprostinil, and wherein the pharmaceutical batch contains at least 2.9 g of treprostinil or its salt.

C. Instituted Grounds of Unpatentability

We instituted trial to determine whether the challenged claims are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. § ²	References
1–9	103(a)	Phares ³
1–9	103(a)	Moriarty, Phares

To support their respective arguments, Petitioner relies on the Declaration of Jeffrey D. Winkler, Ph.D. (Exs. 1002, 1017) and Sylvia Hall-Ellis, Ph.D. (Exs. 1015, 1052); and Patent Owner relies on the Declarations of Rodolfo Pinal, Ph.D. (Exs. 2002, 2025).

D. Related Matters

Patent Owner asserted the '901 patent against Petitioner in *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, No. 1:20-cv-00755 (D. Del.) (“the district court case”). Paper 5, 1.

Petitioner filed IPR2020-00769, challenging the claims of U.S. Patent No. 9,593,066 (“the '066 patent”), a patent in the same family as

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the '901 patent has an effective filing date prior to March 16, 2013, we apply the pre-AIA version of § 103.

³ PCT Application No. WO 2005/007081 A9, published Jan. 27, 2005 (Ex. 1008).

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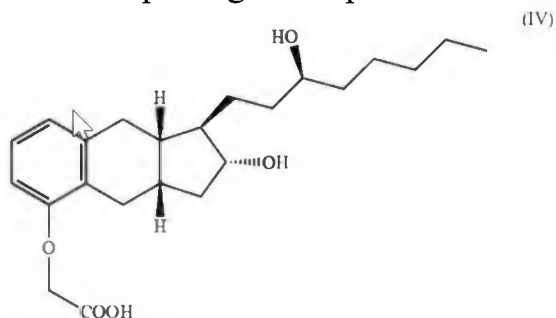
the '901 patent. *Id.* We declined to institute trial in that case.

IPR2020-00769, Paper 7.

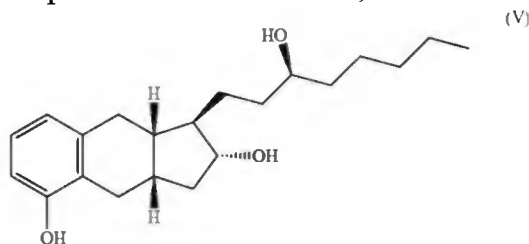
U.S. Patent No. 8,497,393 (Ex. 1004, “the ’393 patent”) is a parent of the ’901 patent. Ex. 1001, code (63). The ’393 patent is the subject of *SteadyMed Ltd. v. United Therapeutics Corp.*, IPR2016-00006 (“the ’393 IPR”). The petition for the ’393 IPR challenged claims 1–5, 7–9, 11–14, and 16–20 of the ’393 patent as anticipated by Phares, and as obvious over Moriarty and Phares. IPR2016-00006, Paper 82 (PTAB March 31, 2017) (“the ’393 Decision” or “the ’393 Dec.”), 7. It also challenged claims 6, 10, 15, 21, and 22 as obvious over Moriarty, Phares, and additional prior art. *Id.*

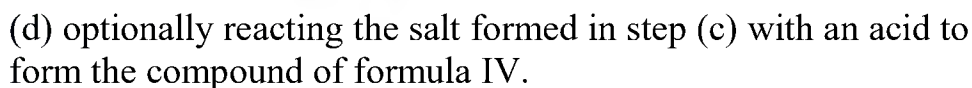
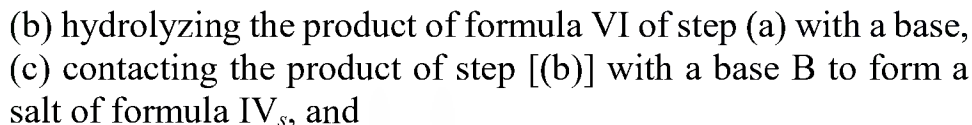
Claim 9 of the ’393 patent recites:

9. A product comprising a compound of formula IV



or a pharmaceutically acceptable salt thereof, wherein said product is prepared by a process comprising
 (a) alkylating a compound of structure V with an alkylating agent to produce a compound of formula VI,





On March 31, 2017, the '393 IPR panel held that the petitioner in the '393 IPR prevailed in all asserted grounds, and that claims 1–22 of the '393 patent are unpatentable. *Id.* at 44, 67, 84, 90. Specifically, it determined that the petitioner there demonstrated the obviousness of claim 9 over the combination of Moriarty and Phares. *Id.* at 44, 68.

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medicine, or a related discipline, or a lesser degree in one of those fields, with correspondingly more experience.” *Id.* at 49. It also found that the relevant skilled artisan “would have had experience in synthesizing and analyzing complex organic compounds.” *Id.*

Dr. Winkler, Petitioner’s expert in this proceeding, also provided testimony in the ’393 IPR. He testified that “an ordinarily skilled artisan would have sought to combine Moriarty and Phares in order to eliminate the intermediate purification step taught by Moriarty, thereby increasing synthetic efficiency and lowering production costs for treprostinil diethanolamine salt.” *Id.* at 46. The ’393 IPR panel credited this testimony, finding that Phares teaches “intermediate purification is unnecessary to the production of treprostinil diethanolamine salt by the disclosed process.” *Id.* at 47; *see also id.* at 50 (“[T]he proposed combination of Moriarty and Phares would eliminate the need for intermediate purification as required by Moriarty alone, and thereby confer efficiency and cost benefits.”). Thus, it determined that “an ordinarily skilled artisan would have sought to combine Moriarty and Phares in order to reap these efficiency and cost benefits.” *Id.* at 50.

The ’393 IPR panel also found “an ordinarily skilled artisan would have sought to make the proposed combination for the independent reason that Phares is directed to improving treprostinil, and the Moriarty process . . . was a well-known way to make treprostinil.” *Id.* It further found “an ordinarily skilled artisan would have a reasonable expectation of success in combining Moriarty and Phares.” *Id.* at 52. The ’393 IPR panel analyzed the evidence of objective indicia, including long-felt but unmet need and

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unexpected results, but found that the evidence did not show nonobvious. *Id.* at 57–67. Thus, it concluded that the combination of Moriarty and Phares renders claim 9 of the '393 patent obvious. *Id.* at 68.

The Federal Circuit affirmed that decision. *United Therapeutics Corp. v. SteadyMed Ltd.*, 702 F. App'x. 990 (Fed. Cir. 2017).

E. The Prosecution of the '901 Patent

During the prosecution of the '901 patent, the applicant submitted the petition for the '393 IPR in an IDS. Ex. 1006, 127. Thereafter, the examiner issued an office action, rejecting then pending claims 1–3, 6, 8, and 9 as anticipated by Moriarty. *Id.* at 118. The examiner found that those claims are product-by-process claims and stated

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process.

Id. at 119 (quoting *In re Thorpe*, 777 F.2d 695, 698 (Fed. Cir. 1985)).

The examiner found that

Moriarty et al disclose[s] a method for preparing treprostinil. Said method comprises the steps of: (a) alkylation of benzindene triol and (b) hydrolysis of the product of step (a) 441 g of treprostinil (a therapeutically effective amount) was prepared at 99.7% purity. Moriarty also discloses removing impurities via extraction and further purification via crystallization. Although the method of Moriarty and the steps recited in the instant claims are not identical, the product obtained is the same.

Id. at 118–19.

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The examiner also rejected then pending claims 10–12 as obvious over Moriarty and Phares. *Id.* at 120. The examiner acknowledged that Moriarty fails to teach the “preparation of a diethanolamine salt of treprostinil” and the “preparation of a pharmaceutical product comprising diethanolamine salt.” *Id.* The examiner, however, found “Phares et al teach[es] preparation of treprostinil diethanolamine by dissolving treprostinil acid and treating it with diethanolamine.” *Id.* at 121.

According to the examiner,

One skilled in the art practicing the invention of Phares would have found it obvious to prepare a diethanolamine salt of treprostinil prepared by the method of Moriarty. Moriarty discloses a method for preparing a treprostinil acid which is a needed starting material for the process of Phares. The resulting salt would meet the limitations directed to pharmaceutical product because treprostinil diethanolamine is the sole claimed component of the claimed pharmaceutical product.

One skilled in the art would have found it obvious to prepare a pharmaceutical product from the treprostinil diethanolamine salt of Phares prepared from the treprostinil free acid that has been obtained by the process of Moriarty.

Id.

In response to the rejections, the applicant cancelled then pending claims 2 and 3, and amended other claims. *Id.* at 96–97. Most significantly, the applicant amended claim 1 as follows:

1. (Currently Amended) A pharmaceutical batch comprising consisting of treprostinil or a salt thereof and impurities resulting from ~~prepared by~~ (a) alkylating a benzindene triol, (b) hydrolyzing the product of step (a) to form a solution comprising treprostinil, (c) contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil, (d) isolating the salt of treprostinil, and (e) optionally reacting the

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salt of treprostinil with an acid to form treprostinil, and, wherein the pharmaceutical batch contains at least 2.9 g of treprostinil or its salt.

Id. at 96.

The applicant also submitted “Patent Owner’s Response and expert declarations from Dr. Williams and [Dr.] Ruffolo” from the ’393 IPR. *Id.* at 98. Relying on the expert declarations, the applicant argued that “a pharmaceutical batch produced according to steps (a)-(e) of claim 1 is different from the product produced by the process described in Moriarty 2004” because “the processes result in products having different impurity profiles, and in fact, the pharmaceutical batch of claim 1 has higher average purity.” *Id.* at 99. The applicant highlighted that

As noted in the Patent Owner’s [’393] IPR Response, the differences between claim 1’s pharmaceutical batch and a product produced according to the process of Moriarty were significant enough to result in FDA’s acceptance of a new purity specification for the commercial product, thus proving that the products are not the same in the eyes of the FDA.

Id. As a result, the applicant requested that the examiner withdraw the anticipation rejection. *Id.*

Regarding the obviousness rejection, the applicant contended that “the differences in the resulting products, as explained above, would not have been expected based on the prior art.” *Id.* According to the applicant, “it would not have been obvious to use the salt formation step of Phares to decrease amounts of stereoisomer impurities of treprostinil” and an ordinarily skilled artisan “would have had no reasonable expectation of success in removing any undesired treprostinil stereoisomer impurities by salt formation and subsequent regeneration of the free acid.” *Id.* at 99–100.

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The applicant again emphasized that “even small changes in impurity are important to FDA.” *Id.* at 100. Thus, according to the applicant, “FDA’s decision to adopt a new purity specification for the resulting product further establishes unobviousness of the presently claimed invention.” *Id.*

Thereafter, the examiner withdrew the anticipation and obviousness rejections “in view of applicants’ arguments, amendments and the accompanying declarations.” *Id.* at 87. And, after the applicant filed a terminal disclaimer to overcome a double-patenting rejection (*id.* at 73–75), the examiner allowed claims 1, 6, and 8–14 (*id.* at 62), and they issued as the challenged claims 1–9. The ’901 patent issued on March 28, 2017, three days before the Board issued the ’393 Decision.

II. ANALYSIS

A. Principles of Law

To prevail in this *inter partes* review, Petitioner “shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.” 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2019).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art;

We analyze the instituted grounds of unpatentability in accordance with these principles.

1. Moriarty

Chemical structure of compound **7**, a tricyclic molecule. The structure consists of three fused rings: A (a benzene ring), B (a cyclohexene ring), and C (a cyclopentane ring). The numbering of the rings is as follows: Ring A has positions 5, 6, 7, and 8; Ring B has positions 4 and 9; Ring C has positions 1, 2, 3, and 3a. A carboxylic acid group (HO-C(=O)-CH₂-O-) is attached to position 5 of Ring A. A hydroxyl group (OH) is attached to position 2 of Ring C. A long alkyl chain (CH₂)₆ is attached to position 1 of Ring C. The stereochemistry at positions 1 and 2 is indicated by dashed and wedged bonds.

Id.

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Id. at 6. The excerpted portion of Scheme 4 of Moriarty illustrates that “[t]riol **34** was alkylated at the phenolic hydroxyl group with use of chloroacetonitrile in refluxing acetone with potassium carbonate (**34** → **35**) and nitrile **35** was hydrolyzed with ethanolic potassium hydroxide to yield UT-15 (**7**),” treprostinil. *Id.* at 8.

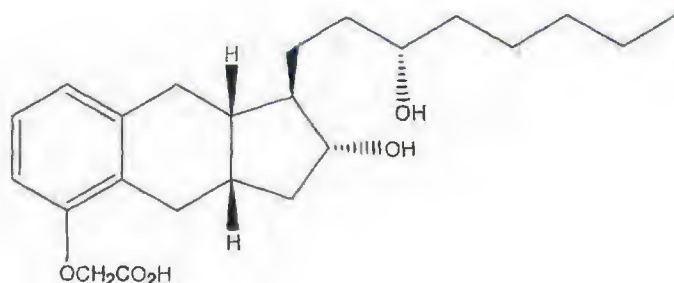
2. Phares

Phares teaches compounds, including treprostinil and derivatives thereof, “and methods for inducing prostacyclin-like effects in a subject or patient.” Ex. 1008, 8.⁵ “Treprostinil is a chemically stable analog of prostacyclin, and as such is a potent vasodilator and inhibitor of platelet aggregation.” *Id.* Phares states that “[t]he compounds provided herein can be formulated into pharmaceutical formulations and medicaments that are useful in the methods of the invention.” *Id.*; *see also id.* at 48 (“provid[ing] for compositions which may be prepared by mixing one or more compounds of the instant invention, or pharmaceutically acceptable salts thereof, with pharmaceutically acceptable carriers, excipients, binders, diluents or the like, to treat or ameliorate a variety of disorders related vasoconstriction and/or platelet aggregation”).

The chemical structure of treprostinil, as shown in Phares, is reproduced below:

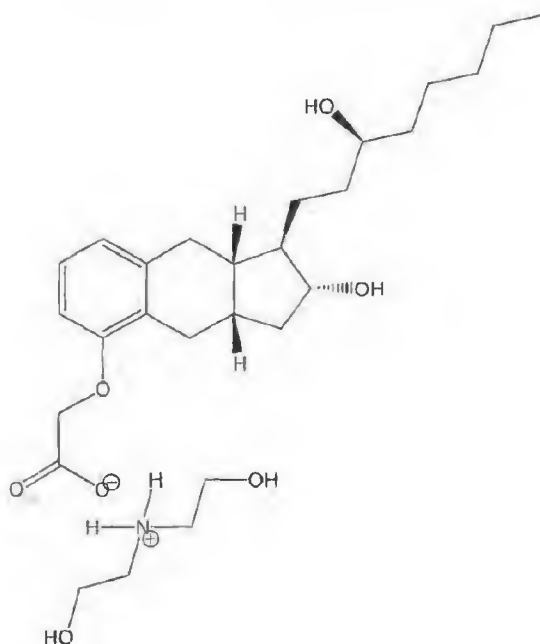
⁵ For Phares, the parties cite to the original page numbers of the exhibits, and not the pagination added by Petitioner. For consistency, we do the same.

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The figure above shows the structure of treprostinil. *Id.* at 8.

Phares teaches that “[a] preferred embodiment of the present invention is the diethanolamine salt of treprostinil.” *Id.* at 9. The structure of the diethanolamine salt of treprostinil, as shown in Phares, is reproduced below:



The figure above shows the structure of treprostinil diethanolamine salt. *Id.* at 96 (claim 49).

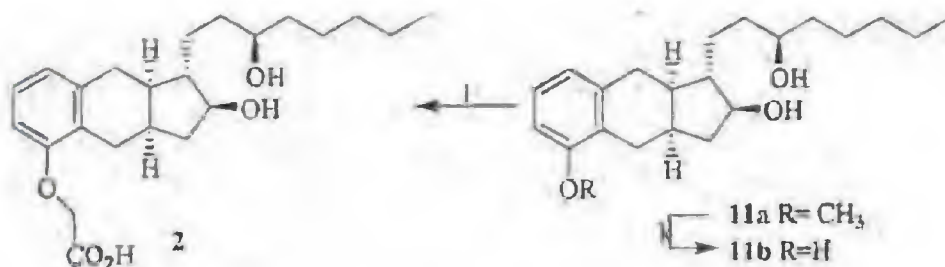
Phares teaches two crystalline forms of treprostinil diethanolamine salt, the metastable Form A and the thermodynamically more stable Form B.

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Id. at 85. Phares states that “[a] particularly preferred embodiment of the present invention is form B of treprostinil diethanolamine.” *Id.* at 9.

Phares teaches the synthesis of (-)-treprostinil, the enantiomer of (+)-treprostinil. *Id.* at 39–40. Specifically, Phares teaches the following reaction procedure:



Id. at 40. The figure above shows the reaction procedure for the conversion of 11b to 2. *Id.* Phares describe it as: “(I) i. ClCH₂CN, K₂CO₃. ii, KOH, CH₃OH, reflux. 83% (2 steps).” *Id.*

Phares further teaches that “the enantiomer of the commercial drug (+)-treprostinil was synthesized using the stereoselective intramolecular Pauson Khand reaction as a key step and Mitsunobu inversion of the side-chain hydroxyl group.” *Id.*, *see also id.* at 39 (“Enantiomers of these compounds . . . can be synthesized using reagents and synthons of enantiomeric chirality of the above reagents.”).

C. Claim Construction

In an *inter partes* review, we construe a claim term “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b). Under that standard, the words of a claim “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e.,

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as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

1. “Pharmaceutical Batch”

In the Petition, Petitioner argues that no construction of claim terms is required and “[a]ll terms should be given their plain and ordinary meaning in the art” at the priority date of the ’901 patent. Pet. 18–19. In the Preliminary Response, Patent Owner emphasizes the difference between a “compound,” as recited in the claims of the ’393 patent, and a “pharmaceutical batch,” as recited in challenged claim 1. Paper 6 (“Prelim. Resp.”), 8. In proposing the construction for “pharmaceutical batch,” Patent Owner relies on the FDA definition of “batch.” *Id.* at 9.

In our Decision to Institute, we generally agreed with Patent Owner’s proposed construction that

The POSA viewing the ’901 patent claims in light of the ’901 patent specification would have understood claim 1’s ‘pharmaceutical batch’ to be a specific quantity of treprostinil (or its salt) that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture, wherein the uniform character and quality is such that it still contains impurities resulting from the method by which it is produced.

Dec. 15–16 (quoting Prelim. Resp. 9). Later, in our Decision Denying Patent Owner’s Request on Rehearing of Decision on Institution, we clarified that “we did not construe the term ‘pharmaceutical batch’ in claim 1 to require storage stability.” Paper 14, 6 (citing Dec. 15–16).

In its Reply, Petitioner argues that Patent Owner’s construction of “pharmaceutical batch” “pulls language directly from FDA regulations” and

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“creates more ambiguity than clarity by introducing terms that themselves would require construction.” Reply 4 (internal quotation marks omitted). According to Petitioner, “a POSA would understand ‘pharmaceutical batch’ to mean one ‘made according to the process recited in steps (a)–(d) and optionally (e), wherein no purification steps appear between alkylation and salt formation.’” *Id.* at 5. Petitioner further argues that “under either construction, Moriarty discloses a ‘pharmaceutical batch’ of 500g.” *Id.* at 6.

As discussed below, we agree with Petitioner that the challenged claims exclude any isolation⁶ between the alkylation and salt formation steps. *See infra*, Section II.C.3. That interpretation, however, flows from the language “contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil,” and not “pharmaceutical batch.” *Id.* As a result, we decline to adopt Petitioner’s proposed construction of “pharmaceutical batch.”

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). Here, we do not need to define the outer bounds of the term “pharmaceutical batch” because the parties’ dispute over this term centers on the issue of storage stability.⁷ Patent Owner argues “the correct construction

⁶ The parties use the terms “purification” and “isolation” interchangeably in the papers. We use the term “isolation” in this Decision.

⁷ The parties agree on the “pharmaceutical” aspect of the term. We note the ’901 patent defines “pharmaceutically acceptable” as “being useful in preparing a pharmaceutical composition that is generally safe, non-toxic and neither biologically nor otherwise undesirable and includes being useful for veterinary use as well as human pharmaceutical use.” Ex. 1001, 5:27–31.

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of ‘pharmaceutical batch’ requires storage stability such that the batch could be stored stably for a period of time customary in pharmaceutical manufacturing.” PO Resp. 43 (citing Ex. 2025 ¶ 78)). Petitioner contends otherwise. Reply 6 (arguing Patent Owner’s construction “imports storage limitations into ‘pharmaceutical batch’ (POR9), but the Board’s construction did not (Dec. at 15-16)”). We agree with Petitioner.

Patent Owner supports its argument, relying on the testimony of Dr. Pinal, who in turn relies on the definitions of “batch,” “in-process material,” and “lot” in the FDA regulations. Ex. 2025 ¶ 78 (citing Ex. 2004, 133–34). Even if we consider the FDA regulations, none of the cited definitions mentions, let alone requires, storage. Thus, we reiterate that the term “pharmaceutical batch” in claim 1 does not require storage stability. *See* Paper 14, 6. This determination as to the scope of “pharmaceutical batch” is sufficient for purposes of this Decision, and we need not further address the term.

2. “Storing”/“Storage”

Claim 6 recites “storing a pharmaceutical batch of a salt of treprostinil as claimed in claim 1 at ambient temperature, and preparing a pharmaceutical product from the pharmaceutical batch after storage.” In our Decision to Institute, we agreed with Patent Owner that the terms “storing”/“storage” “require that the stored material possesses stability sufficient to allow manufacture and which maintains integrity for a sufficient period of time to be useful for the preparation of a pharmaceutical product.” Dec. 17 (quoting Prelim. Resp. 11).

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In its Response, Patent Owner maintains its proposed claim construction. PO Resp. 11. Together with its Response, Patent Owner submitted the Prosecution History of Application No. 13/933,623 (“the ’623 application”) (Ex. 2028). The ’623 application, issued as Patent No. 9,156,786 (the ’786 patent), is the parent of the application that issued as the challenged ’901 patent. *See* Ex. 1001, code (63); Ex. 2028, 264.

Petitioner asserts that Patent Owner’s proposed construction is “inconsistent with its construction of this same term during prosecution of the ’901 Patent’s parent, the ’786 Patent.” Reply 7. We agree.

During the prosecution of the ’623 application, the applicant amended pending claim 1 as following:

1. (Currently Amended) A process for preparing a pharmaceutical product comprising treprostinil or a treprostinil salt, comprising:

combining treprostinil and a base in solution to form a base addition salt;

allowing crystallization of the base addition salt of treprostinil; [[and]]

collecting the base addition salt of treprostinil, storing the collected base addition salt, and preparing a pharmaceutical product comprising treprostinil or a treprostinil salt from the base addition salt after storage.

Ex. 2028, 159. The examiner rejected this claim as obvious over Phares and another prior art reference. *Id.* at 172. The examiner specifically addressed the limitation directed to storing the treprostinil salt. *Id.* at 173–74.

According to the examiner,

The step of storing the treprostinil diethanolamine salt is inherently met by Phares. Examiner is interpreting the term

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“storing” to mean a time period between preparation of treprostinil salt and its use in preparation of a pharmaceutical product. Said limitation is inherently met by Phares. Phares teaches preparation of pharmaceutical products and administration of said compounds to a subject (paragraphs [0049], [0071], [0072], [0074]). It is inherent that some time elapses between preparation of a compound and its use in preparation of a pharmaceutical formulation. Phares describes obtaining an X-ray diffraction spectrum of treprostinil diethanolamine. It is inherent that while obtaining the X-ray diffraction spectrum the compound is being stored.

Id.

In response, the applicant further amended the relevant part of the claim to “storing the collected base addition salt at ambient temperature, and preparing a pharmaceutical product comprising treprostinil or a treprostinil salt from the base addition salt after the storage.” *Id.* at 189. Relying on a Rule 132 Declaration of Dr. Liang Guo, the applicant argued:

[T]he PTO’s interpretation of the term “storing” is too broad even under the broadest reasonable interpretation standard. Even under the broadest reasonable interpretation standard, the PTO may not erase the meaning of a step in a method claim that is tied to the preamble. The claim is directed to “preparing a pharmaceutical product.” In the accompanying Guo Declaration, Dr. Liang Guo explains that a person of ordinary skill in the art would recognize that the term “stored” in the expression “crude treprostinil salts can be stored as raw material at ambient temperature” in paragraph 0046 of the specification as filed means stored for a period of at least three months. Guo Declaration at ¶ 6. Thus, “storing” in the context of “preparing a pharmaceutical product” would be understood by one of ordinary skill in the art to mean a period of at least three months. Based on this understanding of “storing,” Phares clearly does not meet the storing element of claim 1.

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Id. at 193; *see also id.* at 198 (Guo Declaration ¶ 6 stating the same). The examiner, apparently finding this argument persuasive, allowed the claims thereafter. *Id.* at 243–44.

“[A]n invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office.” *Graham*, 383 U.S. 1, 33. “The prosecution history of a related patent can be relevant if . . . it addresses a limitation in common with the patent in suit.” *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305 (Fed. Cir. 2001); *see also Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (“When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation.”).

Here, the Specification of the ’901 patent includes the same language “crude treprostiniol salts can be stored as raw material at ambient temperature” addressed in the prosecution of the parent ’623 application. Ex. 1001, 17:5–6. More importantly, challenged claim 6 recites the same limitation “preparing a pharmaceutical product . . . after storage” the applicant expressly interpreted there. *See* Ex. 2028, 193. Because “the same claim limitation is at issue, prosecution disclaimer made on the same limitation in an ancestor application will attach,” the applicant’s interpretation of “storing”/“storage” during the prosecution of the ’623 application applies here. *See Omega Eng’g, Inc., v. Raytek Corp.*, 334 F.3d 1314, 1333 (Fed. Cir. 2003).

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In the parallel district court case, the court accorded the terms “stored”/“storing”/“storage” their plain and ordinary meaning. Ex. 2035,⁸ 1. Under 37 C.F.R. § 42.100(b), we have considered the district court’s claim construction. In this case, however, the prosecution history, part of the intrinsic evidence, is so unambiguous that we must apply the applicant’s interpretation presented therein. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (“The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.”); *Phillips*, 415 F.3d at 1317.

Petitioner points out that Patent Owner’s expert in the parallel district court case, Dr. Robert R. Ruffolo, opined that, in the ’901 patent, actual storage was not required.⁹ Paper 29, 3–5 (citing Ex. 2034, 130:12–132:4, 132:15–136:11). We acknowledge Dr. Ruffolo’s testimony that claim 6 does not require that the pharmaceutical product be made after storage of the pharmaceutical batch of a salt of treprostinil. *See* Ex. 2034, 136:7–11. Claim 6, however, explicitly recites storing a pharmaceutical batch of a salt of treprostinil, and preparing a pharmaceutical product from the pharmaceutical batch after storage. Thus, we discount the cited Ruffolo testimony on “storage” because it “is clearly at odds with the claim construction mandated by the claims themselves.” *See Phillips*, 415 F.3d

⁸ The parties agreed to submit the claim construction order from the district court case (Ex. 2035) as supplemental information. Paper 40, 2.

⁹ Petitioner asks us to strike “Patent Owner’s Submissions Regarding ‘Storage’” in Patent Owner Response, Sur-reply, and the two declarations of Dr. Pinal (Exs. 2002, 2025). Paper 29, 8. We address this issue below in Section IV.

In sum, we determine that claim 6 requires actual storage, and in view of the applicant's statements during the prosecution of the parent '623 application, we determine the terms "storing"/"storage" in the context of "preparing a pharmaceutical product" require storing or storage for a period of at least three months.

Step (c) of challenged claim 1 recites “contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil.” In its Response, Patent Owner points out that “[t]he claim’s preamble requires the pharmaceutical batch be one ‘consisting of’ what results from the recited steps.” PO Resp. 11. According to Patent Owner, “[t]ogether, this language means treprostinil is not isolated from the solution formed in step (b) before forming a salt in step (c).” *Id.* Petitioner does not contest Patent Owner’s proposed construction. Reply 3 n.2.

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is *not* an explicit limitation of claim 1 of the '901 patent.” Sur-reply 8 (quoting Ex. 2025 ¶ 157 (emphasis added by Patent Owner)).

Patent Owner also relies on the testimony of Dr. Ruffolo in the parallel district court case. *Id.* at 8–9 (citing Ex. 2033 ¶ 15; Ex. 2034, 247–48). According to Dr. Ruffolo, “a POSA would understand that the passage in the Patent Owner’s Response upon which [Petitioner] Liquidia relies is incorrect to the degree it suggests that Examples 2 and 3 describe synthesizing treprostinil without isolating it prior to salt formation.”

Ex. 2033 ¶ 15. Patent Owner argues:

[PO Resp.] at 11 inaccurately suggests that the language of claim 1 means treprostinil is “not isolated” from the solution formed in step (b) before forming a salt in step (c). *See, e.g.*, POR, 15, 29, 34, 53 . . . These statements are unsupported and a POSA would not have understood them as consistent with the claims read in light of the specification.

Sur-reply 8. As a result, Patent Owner states that it “withdraws those statements.”¹⁰ *Id.* at 9; *see also* Paper 29, 1.

Whether Patent Owner is allowed to withdraw its arguments regarding step (c) does not have any effect on our construction of step (c). This is because “[w]hen construing claim terms, we first look to, and primarily rely on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive.”

¹⁰ Petitioner argues that if Patent Owner is permitted to withdraw the statements related to the issue of “not isolated,” then we should strike not only those in Patent Owner Response, as identified by Patent Owner, but also many other statements in the Patent Owner Response, the Pinal Declarations (Exs. 2002, 2025), and the Sur-reply. Paper 29, 1–2. We address this issue below in Section IV.

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Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc., 731 F.3d 1271, 1276 (Fed. Cir. 2013). Here, step (c) of challenged claim 1 requires “contacting the solution comprising treprostinil *from step (b)* with a base to form a salt of treprostinil.” Ex. 1001, 17:27–29 (emphasis added). The claim language itself, thus, dictates that the solution formed in step (b), and not treprostinil isolated from step (b), is the starting material for forming a salt in step (c).

The Specification of the ’901 patent supports our determination. Indeed, the Specification touts that one of the advantages of the disclosed process is that “the treprostinil salts can be synthesized from the solution of treprostinil without isolation,” because “[t]he impurities carried over from intermediate steps (i.e. alkylation of triol and hydrolysis of benzindene nitrile) are removed during the carbon treatment and the salt formation step.” Ex. 1001, 17:1–11. As a result, we agree with the argument presented in the Patent Owner Response that “claim 1 requires the solution in which treprostinil is formed be used directly in the next salt-forming step without isolating treprostinil in between.” *See* PO Resp. 11.

The testimony of Dr. Pinal and Dr. Ruffolo do not change our determination. First, extrinsic evidence in the form of expert testimony, although useful at times, cannot be used to “contradict claim meaning that is unambiguous in light of the intrinsic evidence.” *Phillips*, 415 F.3d at 1324. Because the testimony of Patent Owner’s experts on this issue are “clearly at odds with the claim construction mandated by the claims themselves,” we accord them little weight. *See id.* at 1318.

Second, “extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can

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suffer from bias that is not present in intrinsic evidence.” *Id.* at 1318. Here, Dr. Ruffolo indicated that his testimony was prepared specifically in response to Petitioner’s “documentary evidence that treprostinil in [Petitioner] Liquidia’s LIQ861 is isolated prior to salt formation and cannot infringe.” Ex. 2033 ¶ 4. Thus, the testimony of Dr. Ruffolo on this issue are not sufficiently reliable.

Third, Patent Owner’s reliance on claim 5 of the ’066 patent is unavailing. Patent Owner argues when it “wants to exclude purification from its claim . . . it knows specifically how to do that.” Tr. 56:20–22. Patent Owner essentially invites us to assume that, as an applicant, it always follows the same pattern of claiming. We decline to do so and do not construe step (c) of challenged claim 1 based on the entirely different language in claim 5 of the ’066 patent.

In sum, in view of the intrinsic evidence, including the claim language and the Specification, we conclude that treprostinil is not isolated from the solution formed in step (b) before forming a salt in step (c).

D. Level of Ordinary Skill

In the Decision to Institute, we found “the level of ordinary skill in the art is reflected by the prior art, including Phares and Moriarty.” Dec. 22. Patent Owner argues that the challenged claims “contemplate batch-scale synthesis and late-stage chemical purification.” PO Resp. 23. According to Patent Owner, “scaling up is a separate and difficult process.” *Id.* at 24. Thus, Patent Owner contends that an ordinarily skilled artisan “would have been an industrial chemist or chemical engineer with experience in

Patent Owner relies on the declaration of Dr. Pinal, who testifies that the '901 patent is “focused on the production of pharmaceutical compositions and products, on a commercial batch-size scale.” Ex. 2002 ¶ 91; *see also id.* ¶ 92 (opining that organic and medicinal chemists do not have the “requisite skill set for the large-scale manufacture” of drugs); PO Resp. 24 (arguing an ordinarily skilled artisan is aware of “problems encountered in preparing a commercial-scale pharmaceutical product”).

Patent Owner emphasizes the “distinction between the academic and the practical.” PO Resp. 24 (citing Ex. 2025 ¶¶ 55–63). Dr. Pinal testifies that “[o]ne cannot overemphasize that benchtop synthetic chemistry is not a viable replacement for, i.e., closely related to, the commercial production of pharmaceutical drug products, which is performed to high scale, in a pilot plant, kilo-lab plant, or manufacturing plant.” Ex. 2025 ¶ 55.

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been prepared as described in Moriarty, and used as the active ingredient in Remodulin. Ex. 1001, 1:27–32. And the '901 patent itself describes the Moriarty process as having “[b]atch size: 500 g” with a yield of treprostinil of “~535 g.” *Id.* at 15:38, 16:7, 16:60. Yet, Dr. Pinal characterizes Moriarty as on a “benchtop” scale. Ex. 2025 ¶ 92. This inconsistency casts further doubt over Dr. Pinal’s testimony on this issue.

We also note that Phares teaches not one, but two, clinical studies with treprostinil diethanolamine. Ex. 1008, 82–86. As Dr. Pinal acknowledged during his deposition, pharmaceutical products include those used in clinical trials, even if they are used only in clinical trials. Ex. 1018, 111:17–112:8. Thus, Phares reflects the skill level, even under Patent Owner’s construction.

Patent Owner challenges Dr. Winkler’s qualification to provide expert testimony. *See, e.g.*, PO Resp. 23 n.2 (“Prof. Winkler frames the issues in terms of academic and undergraduate lab organic chemistry because that is where his experience lies.”); Paper 31,¹¹ 4 (“Dr. Winkler is unqualified to testify on the relevant subject matter.”). We are not persuaded.

¹¹ Patent Owner argues that Dr. Winkler does not have qualifications in the relevant field even under Petitioner’s own definition of the skill level, as stated in the Declaration of Dr. Hall-Ellis. Paper 31, 4 (citing Ex. 1015 ¶ 16). Dr. Hall-Ellis, in her Declaration in support of the Petition, testified that an ordinarily skilled artisan is “a medical physicist” with “experience in radiation oncology physics.” Ex. 1015 ¶ 16. Petitioner later filed a supplemental Hall-Ellis Declaration to correct that error. *See* Ex. 1052.

“A person may not need to be a person of ordinary skill in the art in order to testify as an expert under Rule 702, but rather must be qualified in the pertinent art.” Patent Trial and Appeal Board Consolidated Trial Practice Guide¹² 34 (“There is . . . no requirement of a perfect match between the expert’s experience and the relevant field.”). Here, we are satisfied that Dr. Winkler qualifies as an expert witness “by knowledge, skill, experience, training, or education to testify in the form of an opinion.” *See id.*; Ex. 1003.

In sum, after considering the full record developed at trial, we maintain that the level of ordinary skill in the art is reflected by the prior art, including Phares and Moriarty. We further note that our analyses and legal conclusions apply with equal force under the skill level as defined by either party.

E. Obviousness over Phares and Moriarty

Petitioner argues that claims 1–9 of the ’901 patent would have been obvious over Moriarty and Phares. Pet. 49–75. After reviewing the entire record, we conclude Petitioner has shown by a preponderance of the evidence that the combination of Moriarty and Phares renders claims 1–5, 8, and 9 obvious. Petitioner, however, has not shown by a preponderance of the evidence that the combination of Moriarty and Phares renders claims 6 and 7 obvious.

¹² Available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf>.

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1. Claims 1–5, 8, and 9

i. Claim 1

Regarding claim 1, Petitioner points out that Moriarty describes synthesizing treprostinil via the stereoselective intramolecular Pauson-Khand cyclization, and Phares teaches forming treprostinil diethanolamine salt having the same structure as disclosed in the '901 patent. Pet. 53–55 (citing Ex. 1008, 9, 22, 96; Ex. 1009, 1). According to Petitioner, “[t]he combination of Moriarty and Phares discloses the same process steps and product of the '901 patent and as such, the combination of these references would disclose a purity of at least equal purity to that claimed in the '901 patent.” *Id.* at 56 (citing Ex. 1002 ¶ 159). In addition, Phares teaches “the pharmaceutical acceptability of the compounds.” *Id.* at 29 (citing Ex. 1008, 22). Thus, Petitioner concludes “Moriarty in combination with Phares disclose a pharmaceutical batch consisting of treprostinil or a salt thereof and impurities,” as recited in challenged claim 1. *Id.* at 56.

Specifically, Petitioner refers to Moriarty for teaching alkylating benzindene triol 34 to yield nitrile 35, and hydrolyzing nitrile 35 to yield treprostinil. *Id.* at 57, 59 (citing Ex. 1009, 6, 8, 13). Thus, Petitioner contends that Moriarty teaches steps (a) and (b) of challenged claim 1.

Acknowledging that step (c), “the step of reacting treprostinil with a base to form a salt of 7 is not disclosed in Moriarty,” Petitioner asserts “this step is clearly disclosed in Phares.” *Id.* at 54. Petitioner refers to Phares for teaching dissolving treprostinil in a 1:1 molar ratio mixture of ethanol:water and then adding diethanolamine. *Id.* at 54, 61 (citing Ex. 1008, 22).

Petitioner asserts that “a POSA would likely understand the treprostinil acid

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disclosed at page 22 [of Phares] to have been isolated before addition of the base.” *Id.* at 61 (citing Ex. 1002 ¶ 176). But, according to Petitioner, “not isolating the treprostinil before contacting it with a base is obvious based on what is taught by Phares,” and “[a] POSA would be motivated to do so to save a step of isolation.” *Id.* (citing Ex. 1002 ¶¶ 177, 178; Ex. 1008; 40).

Petitioner argues that Phares also teaches step (d) because it is needed to form the disclosed crystalline forms of treprostinil diethanolamine salt.¹³ *Id.* at 62 (citing Ex. 1008, 85–89).

Regarding the wherein clause reciting “the pharmaceutical batch contains at least 2.9 g of treprostinil or its salt,” Moriarty teaches that “[t]he essential requirements for any large-scale, multistep synthesis of a molecule of the complexity of [treprostinil] are very high overall stereoselectivity, high overall chemical yield, and scalability of individual steps to multigram quantities.” Ex. 1009, 3. Petitioner refers to Moriarty for synthesizing 441 g of treprostinil. Pet. 63 (citing Ex. 1009, 13).

Petitioner contends that an ordinarily skilled artisan would have had a reason to combine Moriarty and Phares because “Phares is directed to improving treprostinil, and the Moriarty process . . . was a well-known way to make treprostinil.” *Id.* at 51–52 (citing Ex. 1002 ¶¶ 148, 151). Petitioner further asserts that an ordinarily skilled artisan would have had a reasonable expectation of success in combining the references because “[t]he proposed combination of Moriarty and Phares yields treprostinil diethanolamine

¹³ We do not discuss step (e) because it is an optional step.

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salt . . . via the process taught by Phares,” and “Phares successfully performed precisely that step.” *Id.* at 52–53 (citing Ex. 1002 ¶ 152).

After reviewing the entire record developed at trial, and as explained below, we determine Petitioner has shown, by a preponderance of the evidence, that the combination of Moriarty and Phares teaches each limitation of challenged claim 1. Petitioner has also shown that an ordinarily skilled artisan would have had a reason to combine Moriarty and Phares, and would have had a reasonable expectation of success when doing so.

Patent Owner does not dispute that the combination of Moriarty and Phares teaches steps (a), (b), and (d) of challenged claim 1.¹⁴ Patent Owner also does not dispute that the combined teachings suggest the “at least 2.9 g of treprostinil or its salt” as recited in the wherein clause. Patent Owner, however, challenges Petitioner’s accounting of step (c) of claim 1, asserting that “claim 1’s recited steps differ from Phares and Moriarty because they do not involve isolation of treprostinil intermediate.”¹⁵ PO Resp. 57; *see also id.*

¹⁴ Patent Owner argues that Phares contains “an insufficient disclosure to provide the POSA with enough conditions to successfully recrystallize [tritreprostinil diethanolamine].” *Id.* at 55. To the extent Patent Owner challenges Phares for not being enabling, this argument is unavailing. “Under § 103 . . . a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) (instructing the trial court to reconsider obviousness on remand “without reference to whether [the prior art] is enabled, as enablement of the prior art is not a requirement to prove invalidity under § 103”).

¹⁵ Petitioner asks us to strike this and other arguments because Patent Owner seeks to withdraw some statements related to the “no isolation” argument.

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at 62 (“[T]he recited steps are different from those disclosed in Moriarty and Phares (no isolation of treprostinil after alkylation and hydrolysis steps before forming a salt).”). Patent Owner also asserts that the product from the combination of Moriarty and Phares does not necessarily include the same impurities as recited in claim 1. *Id.* at 62–64. In addition, Patent Owner contends that Phares and Moriarty are directed to different problems. *Id.* at 54–56. According to Patent Owner, Petitioner “has failed to demonstrate that a POSA would have had the requisite motivation and expectation of success.” *Id.* at 58. We address these contentions below.

a. Reason to Combine and Modify

Moriarty teaches synthesis of treprostinil “via the stereoselective intramolecular Pauson-Khand cyclization.” Ex. 1009, 1. Similarly, Phares teaches that “the enantiomer of the commercial drug (+)-Treprostinil was synthesized using the stereoselective intramolecular Pauson Khand reaction as a key step.” Ex. 1008, 40. Thus, we find that the two references are not directed to problems so different that an ordinarily skilled artisan would not have combined their teachings.

Paper 29, 1–2. We address those requests below in Section IV. Our obviousness analysis, however, remains the same regardless of whether we grant Petitioner’s request to strike. This is because, as explained above, based on the intrinsic evidence, we construe claim 1 to exclude isolation between steps (b) and (c). *See supra*, Section II.C.3. Thus, Petitioner must show, with or without Patent Owner’s arguments, that the combined teachings of Moriarty and Phares suggest to an ordinarily skilled artisan to skip the intermediate isolation step.

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Petitioner asserts that one reason to combine Moriarty and Phares is because “Phares is directed to improving treprostinil, and the Moriarty process . . . was a well-known way to make treprostinil.” Pet. 51–52. This assertion is supported not only by the Winkler Declaration (Ex. 1002 ¶ 151), but also by the testimony of Dr. Pinal, Patent Owner’s expert. Indeed, Dr. Pinal recognized, “[t]he end of Moriarty is the beginning of Phares.” Ex. 1018, 135:6; *see also id.* at 135:16–19 (“Moriarty teaches how to make treprostinil and Phares teaches how to take that treprostinil and further modify it to produce other molecular entities.”). As Patent Owner acknowledges, “Phares identifies the diethanolamine salt as a preferred embodiment.” PO Resp. 61; Ex. 1008, 9. Thus, we are persuaded that an ordinarily skilled artisan would have had a reason to start with the treprostinil free acid of Moriarty and convert it into the diethanolamine salt.

Phares teaches “treprostinil as the free acid has an absolute oral bioavailability of less than 10%.” Ex.1008, 2. According to Patent Owner, this shows “[i]f anything, Phares teaches away from the preparation of treprostinil for use as a pharmaceutical product.” PO Resp. 55. We disagree.

As Petitioner argues, an ordinarily skilled artisan would have had a reason to combine Moriarty and Phares because “Phares is directed to improving treprostinil.” Pet. 51. One of the improvements is on the bioavailability. *See* Reply 13 (citing Ex. 1017 ¶ 128); Ex. 1008, 83 (“Based on historical intravenous treprostinil sodium data, the mean absolute bioavailability values for the 0.2 mg, 0.5 mg, 1.0 mg and 2.0 mg doses of UT-15C [treprostinil diethanolamine] were estimated to be 21%, 23%, 24% and 25%, respectively.”).

b. Step (c) and Recited Impurities

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formation.” *Id.* ¶ 151. Relying on the testimony of Dr. Winkler, Petitioner argues that “a POSA would have sought to combine Moriarty and Phares in order to eliminate the intermediate purification step taught by Moriarty, thereby increasing synthetic efficiency and lowering production costs for treprostinil diethanolamine salt.” Pet. 52 (citing Ex. 1002 ¶ 151).

Patent Owner argues that Petitioner “cannot identify support in the asserted art or the background references for these motivations.” PO Resp. 61–62. Instead, according to Patent Owner, Petitioner’s “proffered motivations—increasing synthetic efficiency and lowering production costs—simply restate two advantages identified in the ’901 patent: reducing solvents and labor.” *Id.* at 61.

Patent Owner’s arguments are unavailing because “there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). Thus, Petitioner is not required to cite to prior art for expressly disclosing the elimination of the intermediate isolation step.

This is especially true here because “the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical.” *Id.* at 1368. After all, there is an implicit motivation to combine or to modify prior art teachings when the improvement is technology-independent and the combination or modification “results in a product or process that is more desirable, for example because it is stronger,

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cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient.” *Id.* Such is the case here. We are persuaded that an ordinarily skilled artisan would have had a reason to eliminate the intermediate isolation step, “thereby increasing synthetic efficiency and lowering production costs for treprostinil diethanolamine salt.” Pet. 52; Reply 15; Ex. 1017 ¶¶ 140–144. Thus, we are persuaded that the combination of Moriarty and Phares teaches step (c) of challenged claim 1.

Having decided that an ordinarily skilled artisan would have combined the teachings of Moriarty and Phares, and the combination teaches each required step of challenged claim 1, we turn to Patent Owner’s argument that “[a] product from Moriarty and Phares does not inherently include the same resulting impurities.” PO Resp. 62. We reject this argument because it is based on an incorrect premise.

Patent Owner contends that “[i]nherency requires identity of steps before inherency can be inferred.” *Id.* According to Patent Owner, “the recited steps [of claim 1] are different from those disclosed in Moriarty and Phares.” *Id.* In its Response, Patent Owner alleges that in claim 1, there is “no isolation of treprostinil after alkylation and hydrolysis steps before forming a salt.” *Id.* Patent Owner later seeks to withdraw this statement (Paper 29, 1) but does not explain what other differences exist between the combined prior art teachings and the required steps of claim 1.

As explained above, we are persuaded by Petitioner’s evidence and arguments that the combination of Moriarty and Phares teaches the same process steps as those required in challenged claim 1. Thus, we agree with Petitioner that the product from those steps would include the same resulting

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impurities. *See* Pet. 56; Reply 17 (pointing out that claim 1 recites only “impurities *resulting from*” the steps, without identifying any specific “type” of impurity, and without specifying the solvents and reagent required to perform the steps).

c. Reasonable Expectation of Success

Patent Owner also asserts that Petitioner has not shown an ordinarily skilled artisan would eliminate the intermediate isolation step with a reasonable expectation of success.¹⁶ PO Resp. 30–34. Patent Owner argues Petitioner “ignores the practical realities.” *Id.* at 30. According to Patent Owner, “a POSA would not know if the proposed step elimination would work,” because “in the context of large-scale pharmaceutical manufacturing involving batch production, elimination of an intermediate isolation step has unpredictable impacts on the purity and quality of a final product.” *Id.* at 32 (citing Ex. 2025 ¶¶ 158, 289–297), 34 (quotation marks omitted). Patent Owner’s arguments are unavailing.

¹⁶ Under the ground based on Moriarty and Phares, Patent Owner argues that Petitioner “failed to demonstrate a motivation to combine the references to meet the recited claim limitations with a reasonable expectation of success.” PO Resp. 52; *see also id.* at 58 (the same). Patent Owner, however, does not provide sufficient analysis to undermine Petitioner’s showing of reasonable expectation of success. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (explaining the motivation and reasonable expectation inquiries are different inquiries, and the latter refers to likelihood of success in modifying the prior art to reach the claimed invention). For the sake of completeness, we address here Patent Owner’s arguments related to reasonable expectation of success that Patent Owner proffered under the ground based on Phares alone.

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Relying on Dr. Winkler's testimony, Petitioner argues "[t]he formation of a carboxylate salt, by the addition of a base to a neutral carboxylic acid, and the subsequent addition of a strong acid to regenerate carboxylic acid, as disclosed in claims 1 and 8 are standard chemistry purification procedures." Pet. 22–23 (citing Ex. 1002 ¶ 47); *see also* Ex. 1002 ¶ 48 (citing Exs. 1010, 1011). "More specifically," according to Petitioner, "contacting a carboxylic acid of a prostacyclin derivative, such as treprostinil, with a base to form a salt, followed by the addition of a strong acid to regenerate the carboxylic acid, was a well-known chemical purification technique in the prior art." Pet. 23–24 (citing Ex. 1002 ¶ 49); *see also* Ex. 1002 ¶ 49 (citing Exs. 1012, 1013).

One of the prior art references Dr. Winkler relies on is Kawakami.¹⁷ *See* Ex. 1002 ¶ 49 (citing Kawakami to support the testimony that "contacting a carboxylic acid of a prostacyclin derivative, such as treprostinil, with a base to form a salt, followed by the addition of a strong acid to regenerate the carboxylic acid, was a well-known chemical purification technique in the prior art"), ¶ 157 (the same); *see also* Pet. 23–24 (citing Ex. 1002 ¶ 49), 55 (citing Ex. 1002 ¶ 157). Kawakami describes using dicyclohexylamine to form a crystalline dicyclohexylamine salt of a methanoprostacyclin derivative, in order to purify the methanoprostacyclin. Ex. 1012, 3. It teaches obtaining a dicyclohexylamine salt by "mixing a methanoprostacyclin derivative [I] . . . with dicyclohexylamine in an appropriate solvent." *Id.* at 5–6. According to

¹⁷ Translation of JP 56-122328, published Sept. 25, 1981 (Ex. 1012).

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Kawakami, “[t]he dicyclohexylamine salt of the methanoprostacyclin derivative [I] thus obtained generally has fairly high purity, and the purity can be further improved by recrystallization as needed with the use of an appropriate solvent.” *Id.* at 6. Kawakami states “[t]he dicyclohexylamine salt obtained by the present invention can be easily reverted to a free methanoprostacyclin derivative [I] by conventional methods, and the resulting methanoprostacyclin derivative exhibits excellent crystallinity compared with substances not purified according to the present invention.” *Id.*

Dr. Winkler testifies that dicyclohexylamine is an amine base with similar reactivity to diethanolamine. Ex. 1002 ¶ 49; Ex. 1017 ¶ 108. Dr. Pinal, Patent Owner’s expert, disagrees. Ex. 2025 ¶¶ 180–184. According to Dr. Pinal, even though both dicyclohexylamine and diethanolamine are used as bases to form salts with acidic prostacyclins, they have different miscibilities, which means the salt formation processes using the two bases are “fundamentally different.” *Id.*

On this point, we agree with Dr. Winkler that “Dr. Pinal’s discussion of the relative miscibilities of dicyclohexylamine and diethanolamine is irrelevant, because both compounds are highly soluble in ethanol and the salt formation in Phares is taught in a 1:1 mixture of water and ethanol.” Ex. 1017 ¶ 109. We also agree with Dr. Winkler that “Kawakami teaches the purification of a methanoprostacyclin derivative by salt formation with a secondary amine, which is the same reaction as taught in Phares for the formation of the diethanolamine salt of treprostinil.” *Id.*

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We also reject Patent Owner’s emphasis on “the context of large-scale pharmaceutical manufacturing involving batch production.” *See* PO Resp. 32. As explained above, it is unclear what this context means, especially given that Dr. Pinal characterizes 441 grams of treprostinil in Moriarty as on a “benchtop” scale, even though challenged claim 1 recites “2.9 g of treprostinil or its salt.” *See supra*, Section II.D.

Regardless, Kawakami recognizes that “establishment of an efficient and *industrially viable method* of separating isomers of methanoprostacyclin derivatives is essential in the development of these derivatives as *pharmaceutical products*.” Ex. 1012, 4 (emphases added). It is “[i]n view of” this goal that the Kawakami inventors “succeeded in inventing an extremely simple and *industrially viable purification method*.” *Id.* (emphasis added).

Thus, even taking the context of pharmaceutical manufacturing into consideration, we are persuaded that Kawakami “demonstrates that contacting a carboxylic acid of a prostacyclin derivative . . . with a base to form a salt, followed by the addition of a strong acid to regenerate the carboxylic acid, was a well-known chemical purification technique in the prior art.” Ex. 1017 ¶ 108. As a result, Petitioner has shown an ordinarily skilled artisan would have had a reasonable expectation of success in eliminating the intermediate isolation step.

d. Conclusion

After reviewing the record, we determine that Petitioner demonstrates by a preponderance of the evidence that the combination of Moriarty and Phares teaches each and every limitation of claim 1, and that an ordinarily

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skilled artisan would have had a reason to implement these teachings to arrive at the subject matter of claim 1 with a reasonable expectation of success.

ii. Claims 2–5, 8, and 9

Petitioner provides analysis and citations to record evidence to show Moriarty and Phares teaches or suggests every additional limitation of claims 2–5, 8, and 9. Pet. 64–67, 70–75. Patent Owner does not argue these claims separately. Upon review of Petitioner’s arguments and the evidence of record, we adopt Petitioner’s mapping of the additional limitations of claims 2–5, 8, and 9 as our own findings.

In sum, we determine that Petitioner has demonstrated by a preponderance of the evidence that the combination of Moriarty and Phares teaches or suggests every additional limitation of claims 2–5, 8, and 9.

iii. Objective Indicia of Non-obviousness

Patent Owner contends that objective indicia demonstrates non-obviousness of the challenged claims. PO Resp. 66–69. We disagree.

Objective indicia of non-obviousness guard against hindsight reasoning in an obviousness analysis, and are often “the most probative and cogent evidence in the record.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). As such, objective indicia of non-obviousness must be considered in every case in which they are presented. *Id.* Objective indicia of non-obviousness include commercial success, long-felt but unsolved needs, failure of others, copying, praise in the art, unexpected results, and industry acceptance. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1129 (Fed. Cir. 2000).

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Patent Owner begins by contending that the '901 patent “contains more than mere argument or conclusory statements; it contains specific data indicating improved properties.” PO Resp. 66 (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)). Patent Owner follows that assertion by stating that the Specification “identifies a specific need,” when it explains that “Treprostinil, and other prostacyclin derivatives are of great importance from a medicinal point of view,” and therefore “a need exists for an efficient process to synthesize these compounds on a large scale suitable for commercial production.” *Id.* at 67 (quoting Ex. 1001, 1:66–2:3). According to Patent Owner, “[t]his disclosure emphasizes not only the greater benefit for large-scale synthesis but also the higher purity.” *Id.* (citing Ex. 1001, 6:4–18). Patent Owner asserts also that the Specification “illustrates these advantages with comparative data,” and refers us to other portions of the '901 patent to support that assertion. *Id.* In particular, Patent Owner contends the “storage stability as to the ‘pharmaceutical batch’ of claim 1 and its dependent claims” is an “unexpected advantage.” *Id.* at 68.

We begin by noting, as Petitioner has, that “unexpected advantage” is not a recognized secondary consideration. *See* Pet. Reply 26. Insofar as Patent Owner’s argument is considered be one addressing unexpected results, we find Patent’s Owner’s showing insufficient. As our reviewing court has instructed, to properly evaluate whether a superior property was unexpected, we must first consider what properties were expected. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007). To do so, we consider the results of the closest prior art and compare them to those asserted for the claimed invention. *See In re Baxter Travenol Labs.*, 952

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F.2d 388, 392 (Fed. Cir. 1991) (“[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.”). A showing of unexpected results must be commensurate in scope with the breadth of the claims. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983).

As presented, Patent Owner’s arguments are conclusory at best and do not clearly identify what it considers to be the closest prior art or demonstrate how any alleged unexpected results were unexpected compared with the closest prior art. At most, Patent Owner provides a string citation to portions of the Specification and declaration testimony, without providing a discussion of the alleged evidence and explaining how it supports nonobviousness. Nor does Patent Owner demonstrate adequately that the alleged storage stability advantages were commensurate in scope with the breadth of the challenged. And as explained above, the term “pharmaceutical batch” in claim 1 does not require storage stability. *See supra*, Section II.C.1.

In view of the foregoing, we determine that Patent Owner’s evidence of objective indicia does not sufficiently demonstrate non-obviousness of claims 1–5, 8, and 9.

iv. Conclusion

Upon review of the record as a whole, including Patent Owner’s evidence of objective indicia, and for the reasons discussed above, we determine that Petitioner demonstrates by a preponderance of the evidence that the subject matter of claims 1–5, 8, and 9 would have been obvious over the combination of Moriarty and Phares.

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2. Claims 6 and 7

Claim 6 is directed to “[a] method of preparing a pharmaceutical product from a pharmaceutical batch as claimed in claim 1, comprising storing a pharmaceutical batch of a salt of treprostinil as claimed in claim 1 at ambient temperature, and preparing a pharmaceutical product from the pharmaceutical batch after storage.” Claim 7 depends from claim 6, and specifies that “the salt of treprostinil is a diethanolamine salt.”

Petitioner argues that Phares inherently teaches the limitation of “storing”/“storage.” Pet. 68. Petitioner points out that Phares teaches two crystalline forms of treprostinil diethanolamine salt, Form A and Form B. *Id.* (citing Ex. 1008, 85–89). According to Petitioner,

Phares further discloses that Form B is made from Form A, with full conversion to Form B at ambient temperature after 7 days, 15°C after 11 days and 30°C after 1 day, suggesting stability of the treprostinil diethanolamine salt at these temperatures A POSA would . . . understand that full conversion after 7 days at ambient temperature, as disclosed by Phares, inherently teaches that Form B is stable at ambient temperature and therefore could be stored at ambient temperature.

Id. (internal citations omitted).

Patent Owner contends that Petitioner confuses “*relative* thermodynamic stabilities with actual stability.” PO Resp. 50. According to Patent Owner, “Phares provides no stability data for Form B. That one polymorph is more stable than another does not show that either is stable enough for storage in a pharmaceutical batch.” *Id.* at 50–51. We agree.

Phares teaches two crystalline forms of treprostinil diethanolamine salt, Form A and Form B. Ex. 1008, 85. Phares states that Form B appears to be “thermodynamically more stable” than the “metastable” Form A. *Id.*

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at 85, 89. Phares reaches this conclusion after performing inter-conversion experiments in two different solvents, using Forms A and B material. *Id.*

at 89. In isopropanol, Phares reports full conversion from Form A to Form B at ambient temperature after seven days. *Id.* Dr. Winkler testifies that this “inherently teaches that Form B is stable at ambient temperature and therefore could be stored at ambient temperature.” Ex. 1002 ¶ 203.

Dr. Winkler, however, does not provide a sufficient explanation or cite any support for this conclusory statement.

Petitioner argues that “Phares discloses synthesis and isolation of treprostinil diethanolamine without specifying a temperature.” Reply 19 (citing Ex. 1008, 22). According to Dr. Winkler, “[b]ecause there is no temperature limitation here, a POSA would understand that treprostinil diethanolamine was being isolated at ambient temperature, so that it was stable at ambient temperature.” Ex. 1017 ¶ 150 (citing Ex. 2029, 249).

Petitioner also argues that the fact “Phares mentions no special storage conditions for the treprostinil diethanolamine salt” further suggests nothing other than ambient temperature is required. Reply 20 (citing Ex. 1017 ¶ 153).

We are not persuaded by Dr. Winkler’s testimony or Petitioner’s arguments. As discussed above, we determine claim 6 requires actual storage, and the terms “storing”/“storage” require storing or storage for a period of at least three months. *See supra*, Section II.C.2. Even if an ordinarily skilled artisan would have understood that treprostinil diethanolamine is stable so that it can be isolated at ambient temperature, nothing in Phares suggests the salt would be stable for at least three months.

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Petitioner contends the '901 patent refers to “storing” in a single sentence: “Additional advantages of this process are: (a) crude treprostinil salts can be stored as raw material at ambient temperature”¹⁸ Reply 20 (citing Ex. 1001, 17:4–6). According to Petitioner, this “confirms that a POSA would understand that all crude treprostinil salts can be stored at ambient temperature.” *Id.* “Applying the same knowledge,” Petitioner continues, “a POSA would understand the treprostinil diethanolamine salt described [in Phares] to be storable at room temperature.” *Id.* (citing Ex. 1017 ¶ 155). We are not persuaded.

An invention “must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.” *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985). We cannot use the disclosure of the '901 patent as an instruction manual or template to supply the missing “storing”/“storage” limitation in order to piece together an obviousness theory. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Petitioner does not argue, let alone point to any persuasive evidence of the record to show, an ordinarily skilled artisan would have understood Phares to teach storing treprostinil diethanolamine for at least three months. Thus, we conclude Petitioner has not demonstrated by a preponderance of the evidence that the subject matter of claims 6 and 7 would have been obvious over the combination of Moriarty and Phares.

¹⁸ Elsewhere, Petitioner argues that “the '901 patent does not sufficiently describe or enable this limitation of claim 6.” Pet. 68. We do not address § 112 issues in an *inter partes* review.

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F. Obviousness over Phares

Petitioner argues that claims 1–9 of the ’901 patent would have been obvious over Phares. Pet. 26–48.

Because we determine that Petitioner demonstrates by a preponderance of the evidence that the subject matter of claims 1–5, 8, and 9 would have been obvious over the combination of Moriarty and Phares (*see supra*, Section II.E.1), we do not address the challenge of those claims here. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. Apr. 30, 2020) (non-precedential) (recognizing that the “Board need not address issues that are not necessary to the resolution of the proceeding” and, thus, agreeing that the Board has “discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims”).

For claims 6 and 7, Petitioner presents the same arguments and evidence here as under the ground based on the combination of Moriarty and Phares. *Compare* Pet. 43–45, *with id.* at 68–70; *see also* Reply 26 (relying on the same arguments regarding “storing”/“storage” for both challenges). For the same reason explained above, we reject those arguments. *See supra*, Section II.E.2. Thus, we conclude Petitioner has not demonstrated by a preponderance of the evidence that the subject matter of claims 6 and 7 would have been obvious over Phares.

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III. CONSTITUTIONAL CHALLENGE

Patent Owner contends subjecting the '901 patent to *inter partes* review violates its constitutional rights. PO Resp. 69–71. Patent Owner's arguments on this issue are foreclosed by the decisions in *Celgene Corp. v. Peter*, 931 F.3d 1342, 1362–63 (Fed. Cir. 2019) and *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1986–87, 1997 (2021). As such, we do not further consider or address Patent Owner's arguments.

IV. PETITIONER'S REQUEST TO STRIKE

Petitioner seeks to strike portions of Patent Owner's Response, Sur-reply, and the Pinal Declarations (Exs. 2002, 2025). Paper 29; Exs. 1043–1046.

Petitioner's first request, related to the “not isolated” arguments, is unusual because it is prompted by Patent Owner's requested withdrawal of its own arguments. *See* Ex. 3001. We explained the situation above. *See supra*, Section II.C.3. Briefly, in its Response, Patent Owner argues “treprostinil is not isolated from the solution formed in step (b) before forming a salt in step (c).” PO Resp. 11. Later, in its Sur-reply, Patent Owner attempts to withdraw certain statements related to “not isolated” in the Response. Sur-reply 8–9; Paper 29, 1. Petitioner objected, asking us to deny this request. Ex. 3001; Tr. 16:3–5. Alternatively, Petitioner seeks to strike Patent Owner's proposed construction of step (c) in the Response and “strike all arguments in the Patent Owner Response, expert declarations (Exhibits 2002, 2025), and Sur-Reply relying on the POR's proposed construction.” Ex. 3001; Tr. 16:5–9; Paper 29, 1–2; Exs. 1043–1046.

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As explained above, we determine that, in claim 1, treprostinil is not isolated from the solution formed in step (b) before forming a salt in step (c). *See supra*, Section II.C.3. Because our construction is dictated by the intrinsic evidence, and not by Patent Owner’s arguments, we dismiss Patent Owner’s request to withdraw its statements related to “not isolated” as moot.

Petitioner asks us to strike, in addition to the language Patent Owner seeks to withdraw, large portions of Patent Owner’s Response, together with portions of Patent Owner’s Response and expert declarations, because they allegedly rely on the language Patent Owner seeks to withdraw. Ex. 3001; Tr. 16:5–9; Paper 29, 1–2; Exs. 1043–1046. We deny this request.

In the Petition, Petitioner argues that an ordinarily skilled artisan “would likely understand the treprostinil acid disclosed at page 22 [of Phares] to have been isolated before addition of the base.” Pet. 61. Petitioner, however, asserts that “not isolating the treprostinil before contacting it with a base is obvious based on what is taught by Phares.” *Id.* In other words, Petitioner implicitly construed claim 1 to exclude an isolation step between steps (b) and (c). *See* Tr. 14:6–16:2 (maintaining that excluding isolation “is the actual right construction”). Patent Owner, thus, is entitled to respond to Petitioner’s arguments on this issue, regardless of its own position on how the claim should be construed.

More importantly, we construe claim 1 to exclude isolation between steps (b) and (c). Thus, Petitioner must demonstrate the asserted prior art and the knowledge in the field teach or suggest the elimination of the isolation step, and an ordinarily skilled artisan would have had a reason to eliminate the isolation step, and would have had a reasonable expectation of success

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when doing so. Petitioner cannot circumvent these requirements by striking Patent Owner’s arguments challenging, albeit unsuccessfully, Petitioner’s showing.

Petitioner also asks us to strike Patent Owner’s “Submissions Regarding ‘Storage’” in the Patent Owner Response, Sur-reply, and the two declarations of Dr. Pinal (Exs. 2002, 2025). Paper 29, 8. According to Petitioner, Patent Owner’s expert in the parallel district court case, Dr. Robert R. Ruffolo, testified that, in the ’901 patent, actual storage was not required. *Id.* at 3–5 (citing Ex. 2034, 130:12–132:4, 132:15–136:11). This is inconsistent, Petitioner asserts, with Patent Owner’s position in this proceeding. *Id.* at 2. Even though Petitioner is correct on this point, we decline to strike Patent Owner’s arguments related to “storage.”

As explained above, we determine claim 6, by explicitly reciting “storing,” requires actual storage. *See supra*, Section II.C.2. An expert’s testimony, clearly at odds with the unambiguous claim language, does not absolve Petitioner of its burden to demonstrate that the prior art teaches or suggests this limitation.

In sum, in view of our construction of step (c) and the terms “storing”/“storage” based on the intrinsic evidence, we deny Petitioner’s Request to Strike.

V. PATENT OWNER’S MOTION TO EXCLUDE

Patent Owner filed a Motion to Exclude Exhibits 1002 and 1012, as well as the portions of the Petition and Reply that rely on these exhibits. Paper 31, 2. For the reasons provided below, we deny Patent Owner’s Motion to Exclude.

A. Winkler Declaration (Ex. 1002)

Petitioner relies on the Winkler Declaration (Ex. 1002) to support the arguments in the Petition. Pet. 3. Patent Owner contends that Exhibit 1002 “purports to be a declaration, but without authentication because it lacks the statutorily-required oath or caveat for a declaration.” Paper 31, 3 (citing 35 U.S.C. § 25; 37 C.F.R. § 42.2). Alternatively, Patent Owner asserts that “Prof. Winkler’s declaration warrants no weight because it lacks the required oath or perjury statement.” PO Resp. 17 (citing 35 U.S.C. § 25(b); 37 C.F.R. § 42.63).

Under our Rules, “[e]vidence consists of affidavits, transcripts of depositions, documents, and things” (37 C.F.R. § 42.63(a)), and “[u]ncompelled direct testimony must be submitted in the form of an affidavit” (*id.* § 42.53(a)). “*Affidavit* means affidavit or declaration under [37 C.F.R.] § 1.68 [A] declaration under 28 U.S.C. 1746 may be used as an affidavit.” *Id.* § 42.2.

As Patent Owner correctly points out, Exhibit 1002, the purported declaration of Dr. Winkler, “does not state that the testimony is true or believed to be true, much less reference the penalty for making willful false statements.” PO Resp. 18.

Petitioner does not dispute this deficiency. Instead, Petitioner argues that Patent Owner “waived its argument regarding Dr. Winkler’s declaration under 37 C.F.R. § 42.63, because it did not timely object to the issue with sufficient particularity . . . to allow correction in the form of supplemental evidence.” Paper 32, 1 (internal quotation marks omitted). We disagree with Petitioner.

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First, “[a]ny objection to evidence submitted during a preliminary proceeding must be filed within ten business days of the institution of the trial.” 37 C.F.R. § 42.64(b)(1). We instituted trial on October 13, 2020; and Patent Owner timely filed and served its objections to Exhibit 1002 on October 27, 2020. *See* Paper 10.

Second, “[a] motion to exclude evidence must be filed to preserve any objection.” 37 U.S.C. § 42.64(c). Patent Owner timely filed a Motion to Exclude Exhibit 1002 (Paper 31, 2), and thus, has properly preserved its objections to Exhibit 1002.

Third, Petitioner faults Patent Owner for, in the objections, “generically restat[ing] FRE 802, 901, and 902, and never identified the oath as the issue.” Paper 32, 1; *see also* Tr. 21:19 (“The objections weren’t specific to the perjury statement.”); *id.* at 23:2–4 (arguing that Patent Owner’s objection was “ambiguous”). We disagree.

Patent Owner objected to Exhibit 1002 “under FRE 901-902 as lacking authentication and not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.” Paper 10, 3. According to Patent Owner, Petitioner “does not state that it did not understand the objection . . . , that it sought clarification from [Patent Owner], or that it could not identify how the exhibit lacked authentication.” Paper 37, 1.

During oral argument, Petitioner explained that “we didn’t realize that it was the perjury statement in particular that they were referring to. Or, we didn’t realize that it had been omitted. And so, we looked at the signature and saw that it was there.” Tr. 22:1–4; *see also id.* at 23:3–6 (“[W]hen we saw a lack of authentication [objection], we thought, oh, did Dr. Winkler not

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sign his declaration. We saw that it was signed. We did not realize that they were actually referring to the perjury statement.”).

Counsel for Patent Owner pointed out, and Petitioner did not dispute, “if it’s a declaration, the only thing that would render it inauthentic would be the lack of a signature or an oath[; those] are the only two things it could possibly be.” Tr. 40:3–5. We find Patent Owner’s objection sufficient to put Petitioner on notice that the authentication of Exhibit 1002 is problematic; no more is required of Patent Owner. The fact that Petitioner did not realize the authentication objection is directed to the lack of perjury statement, instead of the lack of a signature, does not make Patent Owner’s objection ambiguous. Thus, we conclude that Patent Owner has not waived its argument regarding Dr. Winkler’s declaration under 37 C.F.R. § 42.63.

Petitioner argues that “any omissions in Dr. Winkler’s declaration with respect to the oath or perjury statement were harmless and have been cured.” Paper 32, 2; Reply 1–2. Petitioner points out that (1) Patent Owner deposed Dr. Winkler on his opinions in Exhibit 1002; and (2) Dr. Winkler “refiled Ex. 1002 as Ex. 1039” and Patent Owner “has not moved to exclude Ex. 1039 or any [of] Dr. Winkler’s opinions therein.” Paper 32, 2; Reply 2. According to Petitioner, Patent Owner “is exalting form over substance in renewing this objection.” Paper 32, 2. We reject Petitioner’s cavalier attitude towards this matter.

First, because Exhibit 1039 was filed without proper authorization, we give it no weight in rendering this Decision. Exhibit 1039 is not a declaration in support of the Reply; instead, it was a “[r]efiled Declaration of Jeffrey D. Winkler, Ph.D. (Ex. 1002)” that is in support of the Petition.

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Paper 42, 4; Ex. 1039, cover page. But, the Petition was filed on March 30, 2020 (Pet. 76; Paper 3, 1), and Exhibit 1039 was filed on March 1, 2021 (Ex. 1039, 81). Petitioner does not explain how a declaration executed eleven months after can support the Petition.

Exhibit 1039 is not proper supplemental evidence either. Under 37 C.F.R. § 42.64(b)(2), “[t]he party relying on evidence to which an objection is timely served may respond to the objection by serving supplemental evidence within ten business days of service of the objection.” During oral argument, counsel for Patent Owner represented, and counsel for Petitioner did not dispute, that Petitioner served Exhibit 1039 on the same day it filed the Reply. Tr. 39:5–23. That is more than four months after Patent Owner timely served the objections to Exhibit 1002. Thus, Exhibit 1039 is not proper supplemental evidence in response to Patent Owner’s objection. *See* Paper 31, 2 (“No supplemental evidence was timely filed to address the[] objections.”).

Second, Petitioner relies on *Google LLC v. CyWee Group Ltd.*, IPR2018-01257, Paper 69 (PTAB Sept. 6, 2019), and *Fidelity Information Services, LLC v. Mirror Imaging, LLC*, CBM2017-00064, Paper 54 (January 2, 2019). Paper 32, 2. As Petitioner recognizes, in those two cases, the Board “grant[ed] party *authorization to correct* unsworn declaration when opposing party cross-examined the expert.” *Id.* (emphasis added). What is critically missing here, however, is that Petitioner never sought leave to correct the unsworn declaration. In fact, Petitioner never brought the issue to the attention of the Board. Instead, it resorted to self-help and “fixed” the issue through a filing without authorization. *See* Tr. 22:5–7.

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Despite our concerns over Petitioner first submitting a defective “declaration,” and then disregarding our Rules when attempting to correct the mistake, we find Patent Owner has suffered no undue prejudice. As Petitioner emphasizes, Patent Owner deposed Dr. Winkler on his opinions in Exhibit 1002. Paper 32, 2 (citing Ex. 2026). Indeed, Patent Owner’s counsel conceded so during the oral argument. Tr. 64:5–6 (“I’d be hard pressed to sit here and say . . . that we suffered a specific cognizable prejudice.”). As a result, we deny Patent Owner’s Motion to Exclude Exhibit 1002.

B. Kawakami (Ex. 1012)

Patent Owner also seeks to exclude Kawakami because, although it purports to be a translation of JP56-122328, it is not authenticated, and not a verified translation. Paper 31, 2, 10–11.

Patent Owner points out that Exhibit 1012 “contains neither the purported Japanese document being translated, nor a verified translator’s declaration.” *Id.* at 10. Patent Owner states that it “timely objected to EX1012 under FRE 402, 403, 802, 803-807, 901, 902, 1001-1003, 1012,” but Petitioner failed to timely serve any supplemental evidence to address these objections. *Id.* at 3 (citing Paper 10, 2–3). Patent Owner also contends that Petitioner has failed to comply with 37 C.F.R. § 42.63(b). *Id.* at 11; *see also* 37 C.F.R. § 42.63(b) (requiring the party who relies on a document in a foreign language to file, with the original document, an English translation, and an affidavit attesting to the accuracy of the translation).

Petitioner argues “Ex. 1012 is exactly the same Kawakami document that was submitted in the IPR2016-00006 as Ex. 1007.” Paper 32, 7. Together with its Opposition to Patent Owner’s Motion to Exclude,

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Petitioner submitted Exhibits 1047–1051, which are “the original Japanese version of Kawakami and declarations attesting to and confirming the accuracy of the translation,” originally filed as Exhibits 1006, 1007, 1011, 1019, and 1020 in IPR2016-00006. *Id.* at 8. According to Petitioner, “[t]he filing of these exhibits remedies any failure to comply with § 42.63(b) or FRE 902(3), which in any event is harmless error.”

As with Petitioner’s omission and later self-help relating to Exhibit 1002, we do not condone Petitioner’s omission and self-help here either. Petitioner contends that Patent Owner “did not move to exclude the identical Kawakami translation in IPR2016-00006, and the Board [in that case] relied on the same translation for an entire ground in its final written decision.” Paper 32, 7. Petitioner fails to recognize that the petitioner in that case properly complied with our Rules, and there was no good-faith basis for Patent Owner to seek any exclusion.

Despite our disappointment over Petitioner’s repeated carelessness, we deny Patent Owner’s Motion to Exclude Exhibit 1012. First, Petitioner relies on Exhibit 1012 through Dr. Winkler’s testimony. Pet. 23–24 (citing Ex. 1002 ¶ 49), 55 (citing Ex. 1002 ¶ 157). Under Federal Rules of Evidence 703, Dr. Winkler may rely on facts or data that are not admissible themselves.

Second, “a comparison between the IPR copies of a reference and a version of the reference proven to be prior art was evidence that the IPR reference was prior art.” *Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1371 (Fed. Cir. 2021) (citing *VidStream LLC v. Twitter, Inc.*, 981 F.3d 1060, 1066–67 (Fed. Cir. 2020)). In the ’393 Decision, the panel

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relied on Kawakami in analyzing one of the obviousness grounds. *See* the '393 Dec. 68–84. Kawakami was properly authenticated in that proceeding. *See* IPR2016-00006, Exs. 1006, 1007, 1011, 1019, 1020. Because a comparison shows Exhibit 1012 in this case is the same as Exhibit 1007 in IPR2016-00006, we deny Patent Owner's Motion to Exclude Exhibit 1012.

VI. PETITIONER'S MOTION TO SUBMIT SUPPLEMENTAL INFORMATION

Under our Rules,

A party seeking to submit supplemental information more than one month after the date the trial is instituted, must request authorization to file a motion to submit the information. The motion to submit supplemental information must show why the supplemental information reasonably could not have been obtained earlier, and that consideration of the supplemental information would be in the interests-of-justice.

37 C.F.R. § 42.123(b).

With our authorization, Petitioner filed a Motion, seeking to submit the Claim Construction Order from the parallel district court case. Paper 38, 1. At the time of the Motion, only the Proposed Order was available. Ex. 1054. Patent Owner does not oppose the Motion in this respect, and submitted the official Order as Exhibit 2035. Paper 40, 2. Patent Owner represents that Petitioner consented to this submission. *Id.*

Our Rules require that we consider “[a]ny prior claim construction determination concerning a term of the claim in a civil action . . . that is timely made of record in the *inter partes* review proceeding.” 37 C.F.R. § 42.100(b). The parties timely filed the Claim Construction Order before

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the oral hearing in this proceeding. *See* Paper 38, 2–3 (arguing the *Markman* Order could not have been obtained earlier). Thus, Petitioner’s Motion to submit the Claim Construction Order from the district court case is granted, and Exhibit 2035 is admitted into evidence in this proceeding.¹⁹

Petitioner also seeks to submit the transcript from the *Markman* hearing at the district court (Ex. 1054). Paper 38, 1. According to Petitioner, “the hearing transcript contains further evidence of Patent Owner’s inconsistencies in its claim construction positions between the tribunals, and the district court’s evaluation of those inconsistencies as likely disclaimer.” *Id.* at 5; *see also id.* at 6–8 (listing “relevant excerpts”).

Patent Owner opposes the Motion in this respect. Paper 40, 2. According to Patent Owner, many of Petitioner’s citations to the hearing transcript “amount to attempts to supplement the record with its own further attorney argument and engage in a game of gotcha regarding allegedly inconsistent statements.” *Id.* at 2–3.

Because we consider the Claim Construction Order from the district court, and because the *Markman* hearing transcript helps to explain how the district court came to its constructions in the Order, we find it is in the interests of justice to admit the hearing transcript into evidence of the record in this proceeding, for just that purpose.

In sum, Petitioner’s Motion to Submit Supplemental Information is granted.

¹⁹ Because Exhibit 1054 is superseded, we expunge it from the record.

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VII. CONCLUSION²⁰

After reviewing the entire record and weighing evidence offered by both parties, we determine that (1) Petitioner has demonstrated by a preponderance of the evidence that claims 1–5, 8, and 9 of the '901 patent would have been obvious over the combination of Moriarty and Phares; and (2) Petitioner has not demonstrated by a preponderance of the evidence that claims 6 and 7 of the '901 patent would have been obvious over either Phares alone, or the combination of Moriarty and Phares.

In summary:

Claims	35 U.S.C. §	Reference(s)	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–9	103	Moriarty, Phares	1–5, 8, 9	6, 7
1–9	103	Phares		6, 7
Overall Outcome			1–5, 8, 9	6, 7

²⁰ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

VIII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–5, 8, and 9 are unpatentable;

FURTHER ORDERED that Petitioner has not demonstrated by a preponderance of the evidence that claims 6 and 7 are unpatentable;

FURTHER ORDERED that Petitioner’s Request to Strike (Paper 29) is denied;

FURTHER ORDERED that Patent Owner’s Motion to Exclude (Paper 31) is denied;

FURTHER ORDERED that Petitioner’s Motion to Submit Supplemental Information (Paper 38) is granted; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

FOR PETITIONER:

FOR PATENT OWNER:

Shaun R. Snader
United Therapeutics Corp.
ssnader@unither.com

EXHIBIT 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

IPR2020-00770
Patent 9,604,901 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

PER CURIAM

Denying Patent Owner's Request for Rehearing of
Final Written Decision
37 C.F.R. § 42.71(d)

INTRODUCTION

Liquidia Technologies, Inc. (“Petitioner”) filed a Petition (Paper 1), seeking *inter partes* review of claims 1–9 of U.S. Patent No. 9,604,901 B2. We instituted trial to review the challenged claims. Paper 7. Thereafter, United Therapeutics Corporation (“Patent Owner”) filed a Response to the Petition (Paper 12), Petitioner filed a Reply (Paper 15), and Patent Owner filed a Sur-reply (Paper 25).

At the conclusion of the trial, we issued a Final Written Decision, determining that Petitioner has shown the unpatentability of claims 1–5, 8, and 9, but not claims 6 and 7. Paper 45 (“Decision” or “Dec.”). Patent Owner timely filed a Request for Rehearing of the Decision as to claims 1–5, 8, and 9. Paper 46 (“Reh’g Req.”). Patent Owner also timely filed a request for Precedential Opinion Panel (POP) review. Paper 47; Ex. 3002. The POP panel denied that request and instructed this panel to consider Patent Owner’s rehearing request. Paper 48, 2.

For the reasons explained below, we deny Patent Owner’s Request for Rehearing.

STANDARD OF REVIEW

The party challenging a decision in a request for rehearing bears the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d). A request for rehearing “must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed.” *Id.*

ANALYSIS

Patent Owner argues that our Decision “relied on inadmissible, unsworn expert statements submitted by Petitioner that, when timely

objected to by Patent Owner, Petitioner failed to timely cure as required by [3]7 C.F.R. § 42.64(b)(2).” Reh’g Req. 2. The unsworn expert statements Patent Owner refers to are from Exhibit 1002, the purported Winkler Declaration. *Id.* at 4.

During trial, the parties briefed, among other issues, whether we should exclude Exhibit 1002. Papers 31, 32, 37. In our Decision, we denied Patent Owner’s Motion to Exclude Exhibit 1002. *See* Dec. 54–58. And in determining that claims 1–5, 8, and 9 are unpatentable, we relied on certain statements from Exhibit 1002. *Id.* at 32–34, 36, 37, 41, 42 (citing Ex. 1002 ¶¶ 47, 49, 148, 151, 152, 159, 174, 176–178).

In its Request for Rehearing, Patent Owner contends that we “erred by considering and relying extensively on the inadmissible original Winkler Declaration.” Reh’g Req. 6. Patent Owner, however, does not identify any matter that we allegedly misapprehended or overlooked. Indeed, in our Decision, we dedicated numerous pages discussing Patent Owner’s contentions regarding Exhibit 1002. *See* Dec. 54–58 (citing 37 C.F.R. §§ 42.2, 42.53, 42.63, 42.64).¹ For example, we acknowledged that “[a]s Patent Owner correctly points out, Exhibit 1002, the purported declaration of Dr. Winkler, ‘does not state that the testimony is true or believed to be true, much less reference the penalty for making willful false statements.’” *Id.* at 54. We also agreed with Patent Owner that it timely objected to Exhibit 1002, which sufficiently put Petitioner on notice, but Petitioner failed to submit supplemental evidence in response by the required deadline. *Id.* at 55–57. Nevertheless, we found that Patent Owner suffered no undue

¹ Our regulations allow us to waive or suspend a requirement of part 42 of our Rules. *See* 37 CFR § 42.5(b).

prejudice, and thus, denied Patent Owner's Motion to Exclude Exhibit 1002. *Id.* at 58.

In its Request for Rehearing, Patent Owner argues that "[t]he Board does not have discretion to allow *unsworn* statements that fail to comply with the statutory sworn-testimony requirements, and it cannot rely on such statements over a timely, uncured objection just by asserting a lack of 'prejudice.'" Reh'g Req. 7. According to Patent Owner, the prejudice suffered is that "the Board actually relied on the challenged document." *Id.* at 8. Patent Owner, however, does not point to where this alleged prejudice was previously addressed. *See* 37 C.F.R. § 42.71(d).

Instead, in our Decision, we explained why Patent Owner suffered no undue prejudice. Dec. 58. Specifically, we pointed out that Patent Owner deposed Dr. Winkler, under oath, on his opinions in Exhibit 1002. *Id.*; *see also* Paper 44, 63:12–15 ("JUDGE SCHNEIDER: Doesn't the fact that you were able to depose Petitioner's expert cure any issues that you might have had with the lack of authentication? MR. CARSTEN: Well, Your Honor, certainly we were able to depose him."). Indeed, the record shows that, during trial, Patent Owner acknowledged that it did not suffer a specific cognizable prejudice. Dec. 58 (citing Paper 44, 64:5–6).

Patent Owner does not identify where we misapprehended or overlooked its arguments as to Exhibit 1002. Rather, Patent Owner disagrees with our decision to deny its Motion to Exclude Exhibit 1002. It is not an abuse of discretion to have made an analysis or reached a conclusion with which a party disagrees. Thus, Patent Owner's Request for Rehearing is denied.

ORDER

Accordingly, it is

ORDERED that Patent Owner's Request for Rehearing is *denied*.

FOR PETITIONER:

Ivor R. Elrifi
Erik B. Milch
Cooley LLP
ielrifi@cooley.com
emilch@cooley.com

FOR PATENT OWNER:

Stephen B. Maebius
George Quillin
Daniel R. Shelton
Foley & Lardner LLP
smaebius@foley.com
gquillin@foley.com
dshelton@foley.com

Shaun R. Snader
United Therapeutics Corp.
ssnader@unither.com

Douglas Carsten
Richard Torczon
Wilson, Sonsini, Goodrich & Rosati
dcarsten@wsgr.com
rtorczon@wsgr.com